Communicating the Iterative Spiral Model of Healthcare Innovation Using Narrative Animation

by
Tziporah Orah Thompson

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Abstract

In an industry dominated by established corporations, current trends show increased innovative technology for healthcare solutions coming from small start-up groups. These start-ups often germinate in an academic setting, relying on the guidance and resources of their educational institution. However, traditional engineering or clinical programs often do not address the requisite bridging between technological innovation and market application. This can lead to a potentially effective healthcare solution failing to reach its patients or users.

In order to address this educational gap, the Johns Hopkins Center for Bioengineering, Innovation, and Design (CBID) developed a model for efficiently navigating the process of healthcare innovation. This model focuses heavily on iteration, stakeholder feedback, and business model de-risking. A narrative animation was created in order to effectively communicate this educational model. The animation introduces the application of the iterative model using pressure ulcers as an example clinical problem. Characters and storytelling were used to stimulate viewer engagement and concept retention.

The goal of this animation was to give potential innovators a starting point and mental model with which to further their understanding of the healthcare innovation process. Feedback from stakeholders was regularly incorporated throughout the animation development process in order to emphasize the clarity and efficacy of concept delivery using narrative animation.

Future directions include providing first-time innovators with a comprehensive educational platform by consolidating important resources into a single webpage. This would include the finalized animation, along with an interactive module, and relevant case studies for reference.

Tziporah Orah Thompson

Chairpersons of the Supervisory Committee

Clifford Weiss, MD, *Preceptor*

Medical Director, The Johns Hopkins Center for Bioengineering, Innovation, and Design

Associate Professor of Radiology, Johns Hopkins University, School of Medicine

Jennifer Fairman, MA, MPS, CMI, FAMI, *Faculty Advisor*

Associate Professor of Art as Applied to Medicine, Johns Hopkins University, School of Medicine

Youseph Yazdi, PhD, *Content Advisor*

Executive Director, The Johns Hopkins Center for Bioengineering, Innovation, and Design

Assistant Professor of Biomedical Engineering, The Johns Hopkins University

Soumyadipta Acharya, MD, MSE, PhD, *Content Advisor*

Graduate Program Director, The Johns Hopkins Center for Bioengineering, Innovation, and Design

Assistant Research Professor of Biomedical Engineering, The Johns Hopkins University

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Introduction

Background

The industry of medical technology (MedTech) encompasses the development and innovation of medical devices such as surgical instruments and diagnostic tools. Development of these products requires not only significant resources, but the combined insights from many disciplines, including engineering, medicine, business and law. Traditionally, large corporations with the infrastructure to support such multidisciplinary development have been the primary source of MedTech production. However, the past decade has seen a dramatic increase in student entrepreneurs driving MedTech innovation through the resources of their academic institutions (Manbachi, 2017). The progress of these students heavily depends on successfully navigating the medical aspect of this industry, which presents far more check-points and pitfalls than generic technological innovation.

The struggles student innovators face when attempting to enter the MedTech industry partly stem from the inherent structure of their academic environment. Traditional engineering programs do not always address the requisite bridging between technological innovation and market application (Yazdi, 2013). Additionally, academic research proposals often focus on where new technology can be applied, instead of on what technology (new or old), can best solve customer's needs (Yazdi and Acharya, 2013). This is the traditional Bench to Bedside Model. In MedTech, not only does this model require a considerable upfront investment, but often that investment can create a bias which attempts to force the technology as a clinical solution, ultimately deemphasizing the needs of the physician or patient. The reverse approach would be a Bedside to Bench Model which begins with identifying a clinical need, inventing a solution, and finally implementing that solution. This is a more reliable strategy, due to the emphasis on filling a need, as opposed to forcing a solution. However, the major pitfall here is that one cannot rely on an initial or surface understanding of a clinical problem. A solution that is initially compatible with a clinician's perspective may not maintain that direction over the course of development, or it may not be compatible from a commercial or regulatory perspective (Yazdi and Acharya, 2013).

Thus, without a reliable strategy to navigate the development process, students encounter obstacles that may result in an excellent product failing to reach its patients. To address these problems, the Iterative Spiral Model of Healthcare Innovation was developed by Dr. Youseph Yazdi, with input from Dr.

Soumyadipta Acharya as well as other CBID faculty (Fig 1) (Yazdi, 2018). It is based heavily on concepts first described for software development by engineers at Cisco in the 1980's (Boehm, 1988), and was adapted for medical device design by Michael Clem and Ethicon, Inc in the 2000's.

Emphasis is placed on stakeholder feedback and business model de-risking. In order to streamline

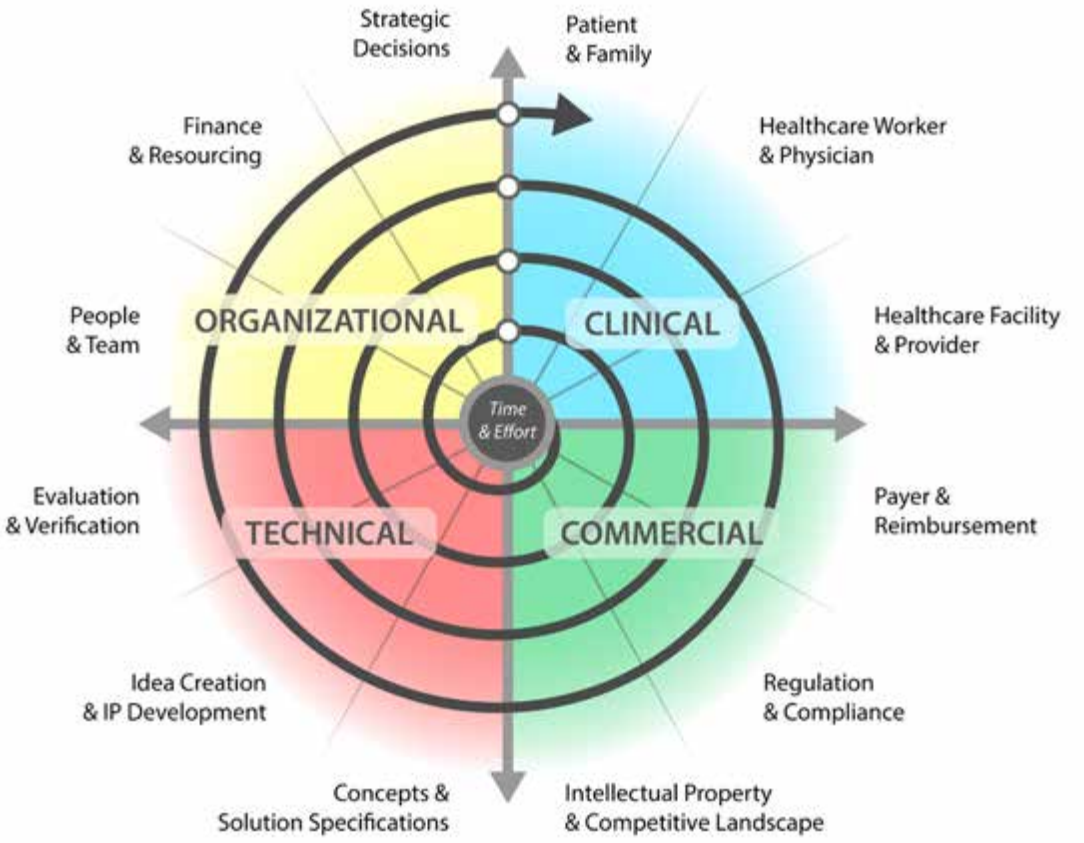


Figure 1. Iterative Spiral Model of Healthcare Innovation. Adapted by Youseph Yazdi. The area under the spiral curve represents the time and effort committed to each sector over time. The white spots represent instances where the project trajectory is evaluated; pivot, continue, modify or kill.

the innovation process, four categories are used to organize issues that are critical to address during development. These categories, or sectors, are Clinical, Commercial, Technical, and Organizational. The Clinical sector houses the perspective of the patient and their family, healthcare workers and healthcare facilities. The Commercial sector addresses issues regarding the competitive landscape for a given clinical problem, reimbursement, payers, business models, and regulations on medical devices. Development of needs specifications, solution concepts, and technical development lie in the Technical sector. Finally, the Organizational sector is comprised of issues regarding strategic objectives, team formation and

management, and financing of the overall project (Yazdi and Acharya, 2013). Each of these sectors is addressed in sequence, with the identification of the clinical problem as the starting point. When one iteration (one turn around the spiral) is completed, the team reaches a moment of pause, which is used as a "reality check." Should the project objective be modified, pivoted, scrapped or continued? The area under the curve of the spiral represents the investment of time and effort in that particular sector. Using this model, a new product makes advances through each sector with gradual and equal attention, building a strong foundation overtime.

Project Objective and Scope

The objective of this project is to create an introductory animation that shows the application of the iterative spiral model to a real-world clinical problem through the use of a narrative. By creating an engaging educational animation that breaks down the complexity of successful healthcare innovation, this project will provide student innovators with a starting point from which they can confidently move forward with their clinical solution. Additionally, by broadly introducing this educational model, viewers will be stimulated to seek further information and resources to better their overall understanding of navigating this industry.

Intended Audience

The primary audience consists of individuals with a medical or bioengineering background who have little to no experience in developing solutions for healthcare challenges. This may include undergraduate students, graduate students, residents, physicians, surgeons and other healthcare providers. The secondary audience is educators who will use this animation as a resource to expand upon curricula that relate to healthcare innovation.

Cartoons as a Tool for Communication

The decision to create an introductory animation was inspired by the popular 1970's animations of "Schoolhouse Rock!" and specifically, their "How a Bill Becomes Law" video (DisneyEducation, 2011). There are several benefits to using this form of animation for education. First, narrative is an extremely powerful teaching tool. By building a narrative arc as a device to convey the primary educational message, the viewer has a framework into which they can place new knowledge, thus improving their understanding

and retention over time (Szurmak, 2013). Second, "the use of cartoon characters may enable readers to engage with subjects which are otherwise perceived as too abstract and detached from everyday life" (Farinella, 2018). This is an important consideration when teaching something as abstract as an educational model. Additionally, we as viewers are more inclined to identify with human representations that are more cartoony (McCloud, 2000). In other words, the more detailed the image of a face is, the more specific and less relatable it becomes. Thus, a narrative animation involving cartoon characters is a robust device for not only breaking down an abstract educational model for healthcare innovation, but also for encouraging viewer engagement and retention.

Materials and Methods

Content Preparation

In order to clarify the direction of the end product for this project, brainstorming sessions were held regularly with the CBID faculty. To become familiar with the goals and vocabulary of the industry, a literature review was necessary. In addition to the literature review for a broad understanding of this process, interviews were held with physicians in the industry to better understand the variability of individual cases. Interview questions included the following:

Background:

Tell me a little about your product.

When was it initiated? Why?

What was your inspiration?

Who else did you work with?

What was the problem you were addressing? How did you identify it?

What was your proposed solution?

Does your current product still reflect that?

Can you speak about that evolution?

What is the current status of your product?

Commercial:

What was the space like when you started?

Were there competitors? How did you compare, where did you fit?

What were your primary sources of funding throughout the process?

Who are the purchasers, and how many have you had?

Who was your biggest non-monetary support?

Did you disclose? When?

Development:

How much did you know about the development process when you started?

Do you know of the iterative innovation spiral? Did it help?

What do you wish you had known?

Did you have any guidance or role model?

What was your biggest setback? (regulatory, financial, technical)

What was your biggest breakthrough?

What was your physical product development process? Did you work with anyone?

What was your minimally viable product?

What surprised you the most?

Closing:

Was it worth it?

Did you ultimately spend more time or more money on your product?

May I contact you again if I have further questions?

Development Process

It was ultimately decided that most suitable end product for this project was a 5 to 6-minute video-tutorial style animation. The following steps were taken to create this animation:

1. Crafting learning objectives
2. Story Outline
3. Choosing an example clinical problem
4. Writing the script
5. Storyboarding
6. Animatic Creation
7. Feedback Survey
8. Final Animation Development

1. Learning Objectives

Due to its introductory nature, the animation could not address all issues relevant to MedTech innovation in any great detail. Thus, it was important to develop learning objectives in order to ensure that the narrative conveyed concepts essential to understanding the iterative spiral model before delving into animation production. Key learning objectives included: A) defining iteration and its application in a clinical setting; B) emphasizing stakeholder feedback and needs; C) early and continued consideration of issues from all stakeholder perspectives D) importance of mentorship and teamwork; E) organizing all issues into themes so as not to neglect anything (clinical, commercial, technical, organization).

2. Story Outline

A story outline was created in order to develop a narrative arc that included a broad view of the iterative method, as well as the appropriate learning objectives. The main points were as follows:

1. Character identifies clinical problem
2. Develops solution with no stakeholder feedback
3. Idea fails (first time)

4. Character seeks feedback
5. Develops new solution with no commercial consideration
6. Idea fails (second time)
7. Mentor steps in to introduce iterative strategy
8. Character iterates once (team grows)
9. Character iterates twice (team grows)
10. Third iteration leads into story wrap-up
11. Future considerations are addressed
12. Character and team are successful

3. Example Clinical Problem

An important consideration for developing this narrative was choosing an appropriate clinical problem to act as narrative framework for describing the iterative process. It was necessary for the chosen problem to provide enough familiar context that a believable solution could be proposed. However, it also could not be so complicated a problem that the development of the solution drew attention away from the significance of the overall process. Pressure ulcers were chosen as a clinical problem due to their simplicity in nature, and prevalence in all hospital settings.

4. Script Writing

Perhaps the most important aspect of this entire project, several iterations of the script were developed in order to accurately and succinctly communicate the overall process. A casual tone was emphasized, representing the narrator as a familiar professor, matching the cartoon quality of the animation. Feedback was incorporated at regular intervals to ensure the learning objectives were described effectively, and vocabulary was used appropriately. It was important that “jargon” common in the field of MedTech not be used, in the event it created more confusion at an introductory level. When use of possibly unfamiliar vocabulary was unavoidable, definitions were included in the animation sequence.

5. Storyboarding

A template was used for ease of storyboard sketching. Several iterations were developed, stimulating script edits for further story clarity. Initially, all storyboards were sketched out by hand, but with major changes, they were scanned and edited digitally with Adobe® Photoshop®. Google Slides were used as an efficient way of sharing storyboards with team members, ensuring storyboard slides were always current.

6. Animatic

Once the storyboards and script were finalized, an animatic was developed. An animatic is a preliminary version of a movie or animation, produced by compiling storyboards with a draft soundtrack. Storyboard files were prepped by developing a numbering system for each asset based on the storyboard sequence, and layering them appropriately in Photoshop for importing into Adobe® After Effects®. Photoshop files were broken up into scenes, and organized as individual compositions in After Effects. A rough draft of the narration was recorded, using Adobe® Audition® to edit timing. The final animatic showed very rudimentary animation, but successfully conveyed a sense of timing and pacing for the overall storyline.

7. Feedback Survey

At this point in the development process, a survey was used to informally assess stakeholder feedback. The animatic served as a perfect tool for imparting the basic message of the project before committing serious time and effort into a more fully developed animation. YouTube was used as the platform for distributing the video, and individuals with backgrounds in medicine and engineering were the target group for informal feedback. The survey questions were as follows:

1. Were you able to understand the message of this animation?
2. Did you learn something new?
3. Was the storyline clear and easy to follow?
4. Were there any parts you found confusing or unclear?
5. Did you find the characters and cartoon style appropriate? Why or why not?
6. Did you find yourself losing interest at any point? If so, where?
7. Were you confused at any point with a symbol, or graphic?
8. Feel free to provide further feedback.

8. Final Animation Development

Narration Recording and Editing

In order to acquire professional voice-over narration in a timely manner, a voice over artist was hired through www.TheVoiceRealm.com. This website has the infrastructure for listening to demos, auditioning talent, hiring, and requesting edits easily online. Audition was used to cut and edit all audio files received from the voice-over artist.

Asset Development and Organization

Assets for the final animation were developed primarily in Photoshop and Adobe® Illustrator®. Photoshop was used to develop characters and backgrounds, while Illustrator was used for the spiral model's motion graphics. Photoshop layers were numbered based on the storyboards, named according to the asset itself, and layered sequentially in compatibility with layer-based animation in After Effects. For animation flexibility and control, each character was separated into several asset layers: body, right arm, left arm, head, face, and eyes. The camera angle primarily focused above the waist throughout animation, negating the need for separate legs or walk cycles. Additional asset layers were separated out depending on the needs of the scene. The heads, faces, and bodies of main characters were consolidated into a separate document in order to efficiently re-use assets. This included each character's assets from several angles: front view, ¾ view, side view, and if necessary, back view (Fig 2). Reusing these assets helped to maintain visual consistency throughout the animation, and promoted time efficiency.

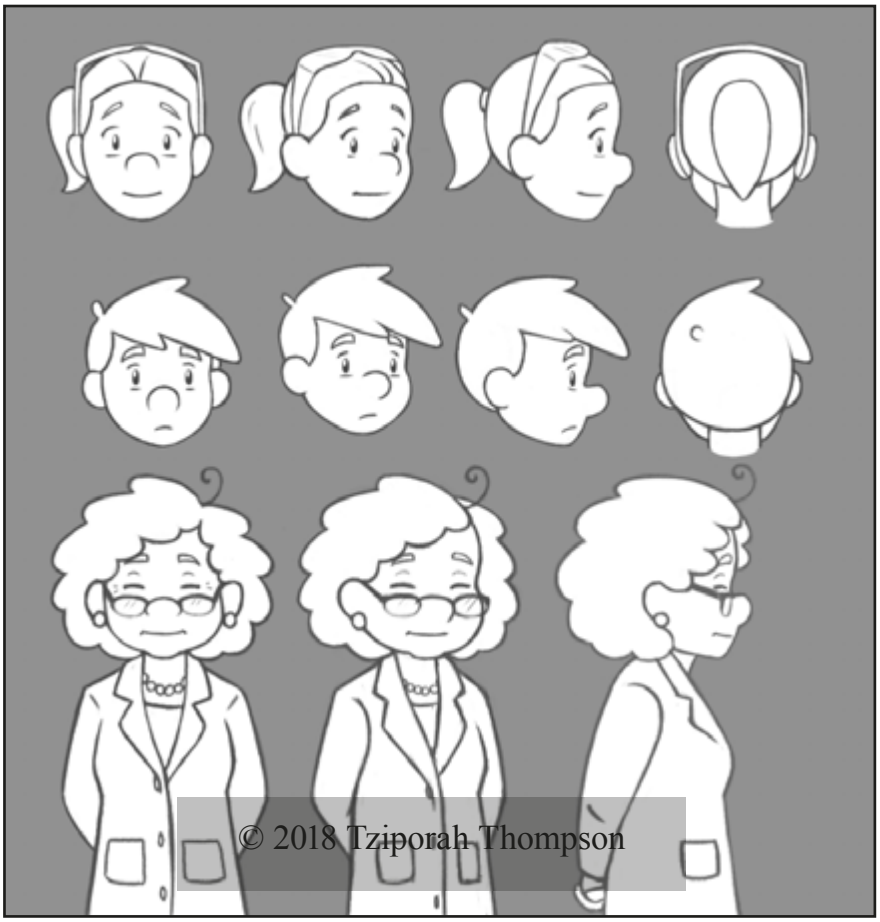


Figure 2. Main character asset sheet

Storyboards were broken up into scenes, based on significant transitions (Table 1). For every two scenes, a new Photoshop file was created in order to reduce the clutter and 'weight' of each file.

Layers within each file were color coded according to their assigned storyboard number and animation progression. Color coding is achieved by right-clicking on the appropriate layer and choosing a listed

Scene	SB	Description
Intro card	0	title of animation
1	1-6	Sammy intro patient appears
2	7-10	Failed first experiment
3	11-13	Feedback from intern
4	14-16	First meet hospital exec
5	17-20	Meet mentor, model intro
6	21	Pressure sore info
7	22-25	First Clin iteration
8	26-28	First Comm iteration
9	29-32	First Tech and Org iteration
10	33-34	Pause, expand to second iteration
11	35-37	Second Clin and Comm
12	38-41	Second Tech, Org, and pause
13	42-44	Third Clin and Comm, with continuation
14	45-47	Diagram development
15	48-49	Wrap up
Credits		scroll through article

Table 1. Storyboard to scene breakdown

color. In After Effects, a new composition was created for every scene. After importing and organizing layers to match the Photoshop files, layers were similarly color coded by right-clicking on the colored squared to the left of the layer number. Since each scene contained roughly 40 layers, this allowed for ease of visual scanning and maintaining consistency between Photoshop and After Effects (Fig 3). Asset layers were then linked to each other for efficiency of positioning and scaling (Fig 4). Face and eyes were linked to the head, while the head and arms were linked to the body. Assets were also developed in such a way that each animation progression acted as an essential key-frame. Independently, this allows for a basic level of simplified interpolation-based animation, while also laying the foundation for developing in-between animations for future iterations.

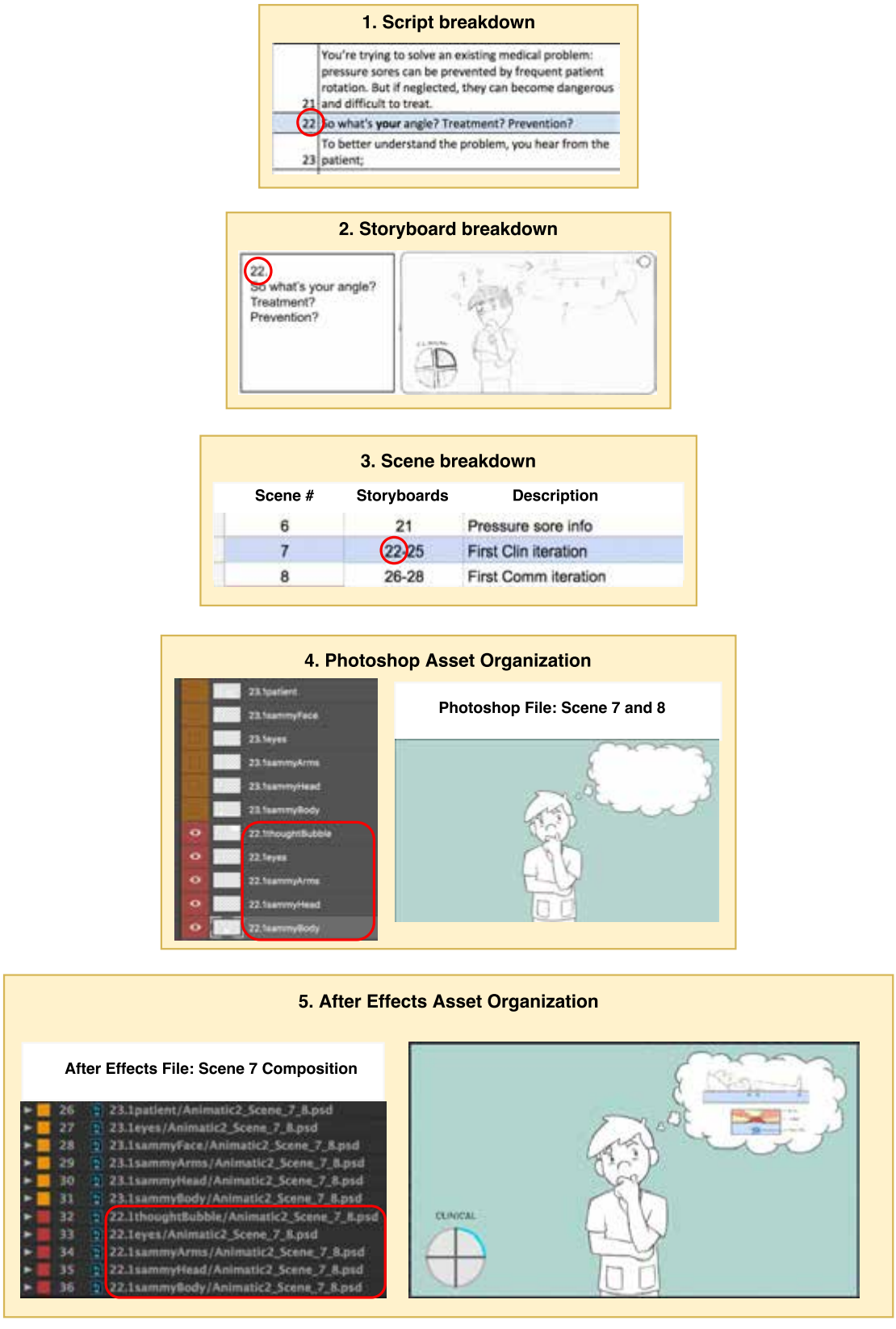


Figure 3. Flowchart of file organization. Text not intended to be read.

Figure 4. Linking assets in Adobe After Effects. Text not intended to be read.

Sketch and Toon Effect in Cinema 4D

Towards the end of the animation, a 3D model was developed with Cinema 4D in order to create a smooth transition between the spiral model graphic and the headquarters of the main character's business (Fig 5). In order to visually incorporate the 3D model into the flat 2D animation, a material was created with a luminance channel set to a light gray (Fig 6). This gave the model a flat color without any visible shading or modeling, similar to the style of the animation. The Sketch and Toon effect was then turned on in the render settings, and the following lines were checked: outline, creases, intersections, and splines (Fig 7). This provided sufficient strokes to define the simple shape of the model. Within the Sketch and Toon material settings, several changes were made. In the Color channel, Texture was checked and a noise filter was added in order to emulate the look of a drawn pencil line (Fig 8). Additionally, within the Thickness channel, "Along Stroke" was checked which provided a variation in stroke, emulating the changing width of a pencil line due to pressure (Fig 9).

Figure 5. 3D model for Scene 15

Figure 6. 3D model material settings. Text not intended to be read.

Figure 7. Sketch and Toon render settings. Text not intended to be read.

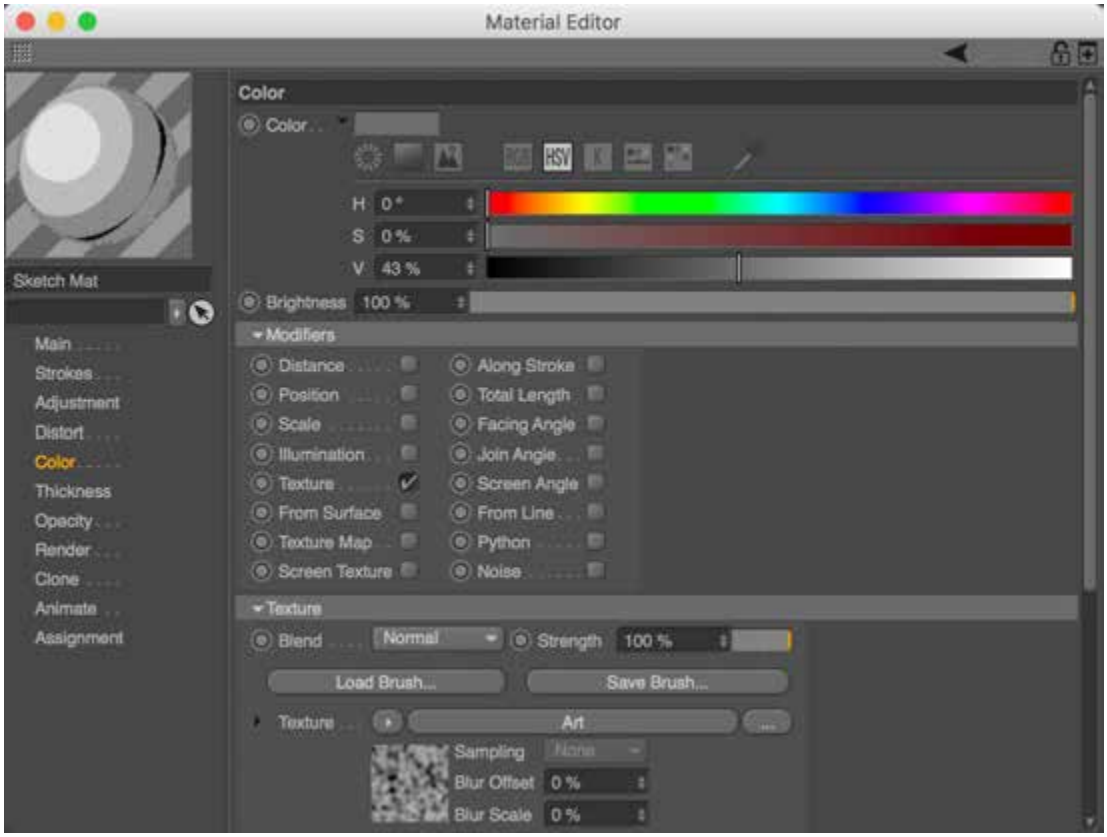


Figure 8. Color settings for Sketch and Toon material. Text not intended to be read.

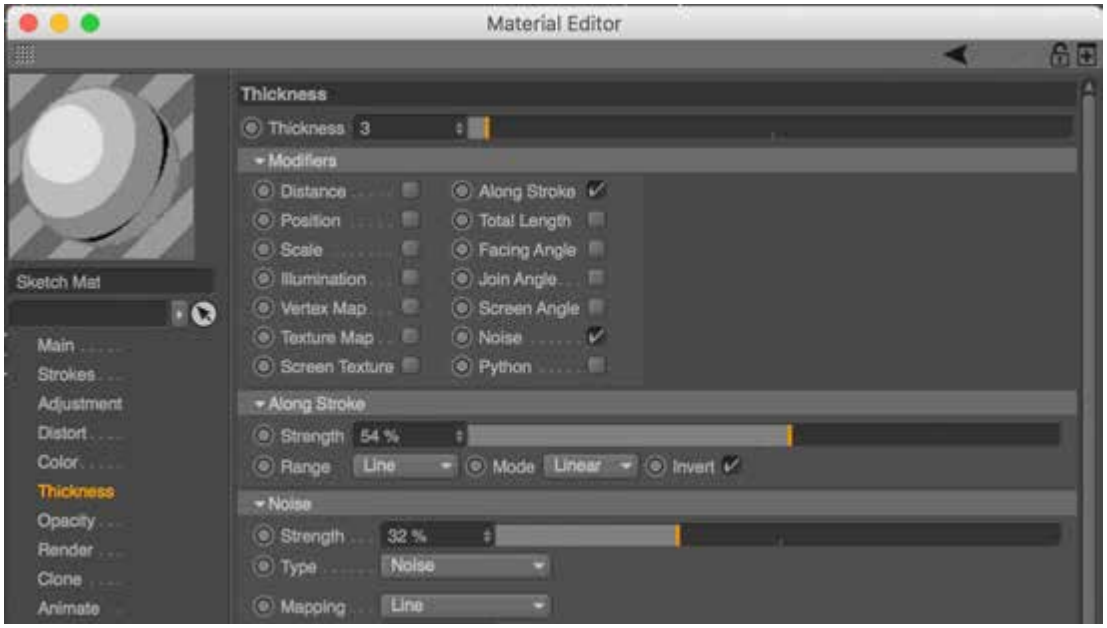


Figure 9. Thickness settings for Sketch and Toon material. Text not intended to be read.

Animating Iteratively

In accordance to the educational content of this project, by taking an iterative approach there was a usable product at every major stage of the animation's development. By addressing every aspect in gradual iterations, the entire project builds up in unison, allowing for a stronger end product. This results in usable product at all points in development, as opposed to rendering out one portion to completion, and ending up with only small usable portions. The main iterations planned for development were as follows:

1. Animatic from storyboard sketches
2. Basic animation with line-drawing assets and didactic spot color
3. Iteration #2 with background music and sound effects
4. Iteration #3 with lip syncing
5. Iteration #4 with full color
6. Iteration #5 with in-between animation

For the scope of this project, Iteration 4 was the planned outcome.

Sound Effects and Background Music

Sound effects for the animation were sourced from Freesound.org, Soundeffectsplus.com, and Youtube.com, all of which provide sound effects in the public domain. Public domain background music was also sourced from Youtube.com. Additional sound effects were made using original recordings. All sound files were edited in Audition, and imported into After Effects.

Lip Syncing Animation

Due to the fact that the narrator of this animation also appeared as the mentor character, there were several scenes where it was necessary to have the mentor's lips match the overlying audio track. In order to accomplish this, the 2D animation program TVPaint was used for its frame-by-frame animation interface. After completing the basic character animation in After Effects, the scenes that required lip syncing were rendered out selectively, and converted to AVI file using Cloudconvert.com. These files were then imported into a new TVPaint project document set to 1920 x 1080 px, 24 frames per second (fps). The waveform of the animation's audio track was visible along the timeline, and the notation bar was used to demarcate phonetic changes (Fig 10). Using a lip-sync chart created by Dominic Panganiban as reference (D0MICS, 2013), mouth shapes were individually drawn frame-by-frame on a layer above the original animation. Once the scene was completed, the layer containing the original animation was made invisible, and the layer containing the mouth shapes was exported as a PNG series with an alpha background

(RGBA, background unchecked). These files were then imported into After Effects as a PNG sequence. After importing the sequence, the frame rate of the sequence was changed from the default (30 fps) to 24 fps. This was accomplished by right clicking the sequence in the project source, selecting Interpret Footage>Main, and typing in the correct frame rate in the active field. This is important for ensuring that the lip-syncing animation matches perfectly with the main animation.

Figure 10. Lip syncing in TVPaint. Phonetic changes were marked in the notation bar (A) to match audio cues in each frame. A new layer was created (B) above the original animation. Mouth shape chart by Dominic Panganiban was used as reference (C). Text not intended to be read.

Liveliness in Interpolation Animation

Several simple techniques can be used to elicit natural, life-like motion while using an interpolation based, non-traditional animation style. The most common technique used in this animation was selective scale key-frames to emulate traditional squash-and-stretch animation principals. For example, if a

character were to change positions from a hand on their chin to an outstretched hand, there would be three primary assets involved: the body, the arm position before, and the arm position after. Using opacity key-frames, this transition can be made easily (hand on chin 100% to 0% opacity, at the same time as outstretched hand 0% to 100% opacity). However, the fade transition on its own is lifeless and stiff. By adding three scaling key-frames to the body asset, a subtle squash and stretch can be induced (Fig 11). It is important that the arm layers be linked to the body layer, so that all assets scale in unison. This also negates the need to create key-frames for every asset individually. Another important consideration is the layer's anchor point. By default, the anchor point of a layer in After Effects is either centered on the composition, or the layer bounding box. Due to the fact that squash and stretch emanates from the ground

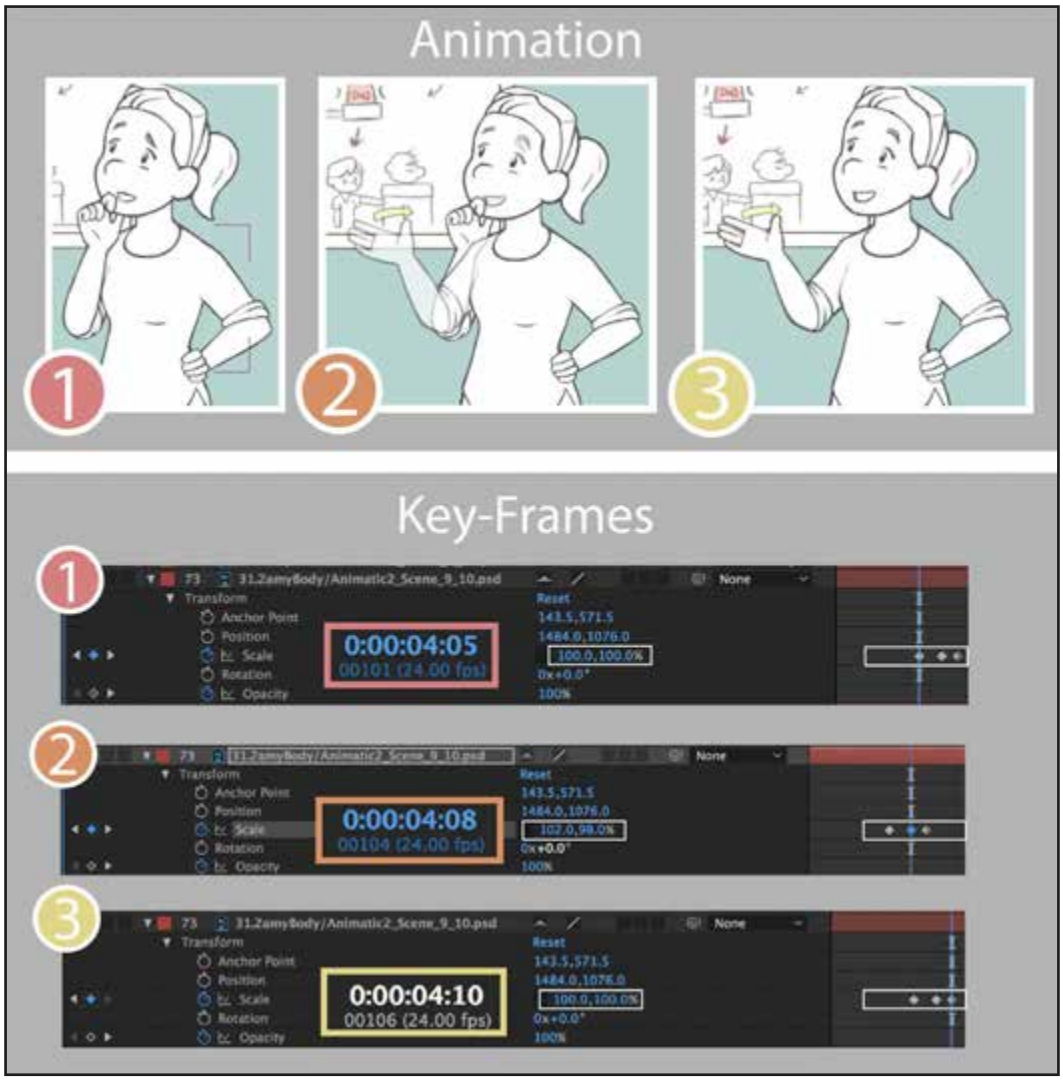


Figure 11. Squash and stretch technique in After Effects

of the character's position, the anchor must be moved to the very base of the body layer's bonding box.

The first scaling key-frame is the normal scale of the asset, and should be position directly in line with the 0% opacity key-frame of the second arm position. When the second arm position reaches 100% opacity (roughly 3 frames later), a second scaling key-frame is placed. Scaling was unlinked in order to freely transform proportions. If the original scale of the body layer is 100% by 100%, then a simple squash increases the width by 2%, and the reducing the height by 2%, resulting in a scaling key-frame of 102% by 98%. A third scaling key-frame is placed roughly two frames after the second, returning the body layer to 100% by 100%. This results in a quick squash of the character which gives their movement transitions a touch of liveliness. This same technique can be used on just the head layer of the character (ensuring the anchor point is at the base of the neck and that they face and eye layers are linked to the head), when blinking. The slight squash provides enough movement that a scene can carry on without change, while still displaying a "living" character. Additionally, due to the fact that Ms. Swizzle's legs were not visible beneath her white lab coat, this technique provided an excellent substitution to a full walk cycle when she moves across the screen. By reversing the dimensions (98% by 102%), a slight stretch upwards can be achieved, which results in a slightly surprised or excited motion. Further subtly can be added by skewing the stretch in horizontal directions in order to add emphasis to a movement.

A second technique to add simple, convincing character motion is the puppet warp tool in After Effects. This provides an easy method for creating and animating the positions of several pinned anchor points on one layer. This technique was used to add quick, subtle motion to the hands of characters in the animation when typing or writing.

Traditional Aesthetic

In order to emphasize the stylistic quality of animation created with traditional artistic tools, a high quality (over 1920x1080 px) image of watercolor paper was layered onto the overall animation. The image was imported onto a shape layer in After Effects and set to blend mode "multiply" at 50% opacity. A second shape layer was created underneath this texture, but over the entire animation composition. This shape layer had a very pale orange-grey fill, set at blend mode "multiply" and 75% opacity. An inverted ellipses-shaped mask was created and feathered to 250x250, centered on the composition. This created a subtle vignette, essentially aging the paper texture. A soft drop shadow effect was used on each scene composition in order to create the impression of cut-out paper characters against a backdrop (Fig 12).

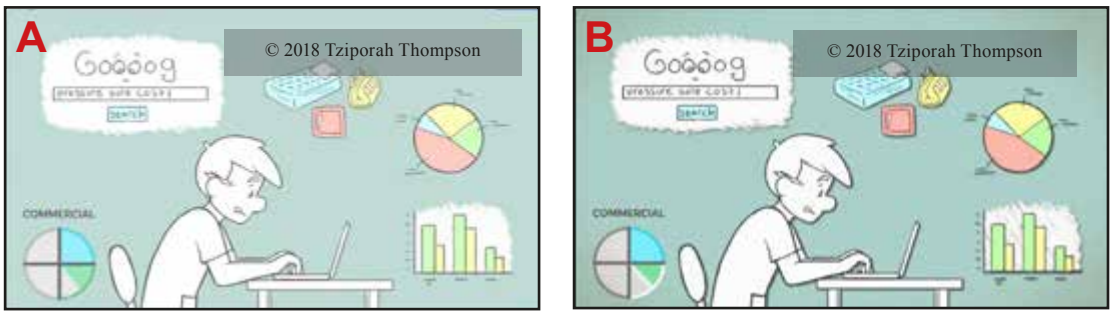


Figure 12. Traditional aesthetic. Before (A) and after (B). Text not intended to be read.

Together, these techniques emphasized the aesthetic of a traditional style.

Video Hosting and Closed Captions

Vimeo was used as the hosting platform for the completed animation. The advantage here is the ability to update a video file without changing the associated URL. This is not a capability that Youtube.com currently supports. Remote feedback could easily be incorporated without having to generate new links with every iteration. Unlike Youtube, however, Vimeo does not support its own closed captioning platform. A third party platform is needed to generate a VTT file. This is a file type which associates written phrases (ideally no longer than 42 characters) with time stamps throughout the course of a video. In this case, Amara.com was used to manually sync script phrases with the appropriate sound cues. The VTT file was then exported, and uploaded into the Vimeo file.

IRB Submission

In order to test the educational efficacy of the introductory animation, a protocol was submitted through the Institutional Review Board's portal for the Johns Hopkins School of Medicine: https://e-irb.jhmi.edu. Survey questions were drafted in order to assess viewer confidence with the process of solving healthcare problems before and after viewing the introductory animation. Due to the purely survey based nature of this protocol, it received "exempt" status. Survey questions were as follows:

Pre-Video

1. I am a... (choose one)

   Medical Student; Resident; Fellow; Faculty; Nurse; Technologist; Administrator; Other

2. Have you ever had an idea for solving a healthcare challenge or problem?

   Yes No

3. If yes, would you feel ready to put it into action and see it through?

   Not ready at all |----------| Very ready

4. How comfortable are you with the design process for healthcare innovation?

   Not comfortable at all |----------| Very comfortable

5. How well do you understand the iterative model as applied to healthcare innovation?

   No understanding |----------| Very competent

Post Video

1. Do you have any new ideas for solving a healthcare challenge or problem?

   Yes No

2. How ready do you feel to put an idea for a healthcare solution into action and see it through?

   Not ready at all |----------| Very ready

3. How comfortable are you with the design process for healthcare innovation?

   Not comfortable at all |----------| Very comfortable

4. How well do you understand the iterative model as applied to healthcare innovation?

   No understanding |----------| Very competent

5. Please feel free to provide more feedback, including any memorable phrases from the video, information you found thought provoking, or what you would like to see for future directions.

This protocol has been submitted and is currently under review.

Results

Content Surveys

The content surveys provided a broader understanding of the process of medical device development. Two physicians were interviewed in depth on the process of their proposed devices for solving specific clinical problems. Although both projects generated industry excitement, one project is currently in the process of being developed, while the other has lost all momentum. The details behind these processes provided excellent perspective regarding the inherent variability of this industry. Both physicians worked closely with CBID students, and had a good understanding of the iterative process. This facilitated successful ideation, however variables of interpersonal interaction greatly affected the success or failure of the respective projects (completed surveys in Appendix A).

Animatic

The animatic was created using the completed storyboards (Appendix C) paired with a draft recording of the finalized script (Appendix B). The title card displays "The Iterative Spiral Model of Healthcare Innovation." The narration begins, cueing the main character (Sammy) to pop into view as a confident medical student. With another narration cue, he turns into a frazzled third year medical student, and is placed in the context of a short-staffed hospital with rampant pressure sores. A patient appears before him, and expresses pain in his elbow, heels and sacrum, before a nurse appears to shove Sammy out of the way. Concerned, Sammy initially attempts to solve the problem of pressure sores with a very limited understanding of the overall issue. His first solution is to cover all potential pressure sore areas with pillows, and he appears lying on a bed in such a state. He quickly realizes that this leads to very limited mobility and dexterity, and his pillow covered arm is shown knocking over a glass of water on a bedside table.

His next attempt involves seeking advice from his supervising resident in the hospital. The resident explains that any pressure over time will result in a pressure sore. With this slightly better understanding of the problem, Sammy develops a new solution with the resident involving a bed which uses air jets to separate the patient from the bed itself, thus reducing pressure. Sammy is excited about the potential of this solution, but the resident brings up the issue of paying for the development of such a complex product. As per the resident's suggestion and with hopes of receiving more support, Sammy seeks out a

meeting with a hospital executive. The executive's door slams into place, startling Sammy and covering the resident. The executive bluntly explains to Sammy how his solution is unmarketable and financially inefficient, and slams the door in his face.

A now bereft Sammy is met by Ms. Swizzle, the mentor character and narrator, who provides a strategy for navigating this development and problem-solving process. Ms. Swizzle sits Sammy down in a desk-chair, and continues narrating as graphics appear above their heads to describe the iterative process. This begins with sixteen relevant issues rapidly popping into view. These issues are then organized into four main categories; Clinical, Commercial, Technical, and Organizational. They are referred to as "sectors," at which point the four encompassing categories merge into one circle. Ms. Swizzle explains that all the issues cannot be addressed at once, so an iterative approach is necessary, at which point arrows appear to show a turn around the circle. As concentric circles appear, "iterative" is defined. The circles expand outwards to depict the nature of this process. Axes separating the sectors also expand and are labeled with "Effort & Time." Stakeholder feedback is also emphasized and a definition box appears in the corner to briefly explain the meaning of "stakeholders." At this point, the characters have faded out, and the center graphic becomes a simplified corner icon, focusing on the Clinical sector.

A series of visuals is used to explain details regarding the clinical problem being addressed; pressures sores are easy to prevent, and hard to treat if neglected. With this background, Sammy begins seeking feedback from the patient and the nursing staff in order to better understand the clinical problem. As he speaks with them, he takes notes, and the Clinical sector of the corner icon begins to slowly fill, showing his progress in the iterative process. The patient expresses his need to be comfortable, while the nurse expresses the need for some sort of warning to indicate the potential development of a pressure sore. This sparks an idea for Sammy to create a device which can be placed on the potential sore area, and warn the nurse before the development of a sore with an alarm.

His excitement to move forward with this idea is put on hold by the reappearance of Ms. Swizzle, who suggests researching issues in the Commercial sector before moving forward. This brings to mind Sammy's confrontation with the hospital executive, and the importance of considering who pays for the product. A laptop and desk appear, and Sammy sits down to perform market research, as the narration suggests important questions to consider: "what's already available in the market? How well does it work? How will your innovation be better?" Concurrently, graphics appear to indicate Sammy's research

progress, and the Commercial sector of the corner icon fills up. A final graphic shows a GAP analysis, while narration describes how the design of a product will be shaped by how currently existing products fail to fully solve the clinical problem.

With the Commercial sector completed, Ms. Swizzle appears again to introduce the next sector: Technical, time to build something. Sammy calls an engineering friend (Amy), who appears on a split screen wearing a Bluetooth headset and holding a soldering iron. This transitions to them standing together before a whiteboard, where Sammy explains his idea, and Amy provides the suggestion of using Bluetooth instead of wires to connect a pressure sensitive patch to an alarm device. They then sit down at a table to build a rough prototype. Sammy presses a Bluetooth enabled pressure sensing patch which triggers a large red alarm held by Amy. The Technical sector fills up over the course of this process. With a handshake between Sammy and Amy, their team is officially formed. This is indicated as an important part of the Organizational sector, which involves strategizing for the future direction of the overall project. Sammy and Amy clean up the table and discuss grants and a start-up company.

As the final sector is filled, the first iteration is completed and Ms. Swizzle reappears to explain that now is the time to pause and take stock of the situation. Is their current solution still solving their original problem appropriately? Sammy and Amy turn to consider the whiteboard, and a fist-bump of confirmation is exchanged. They fade out as Ms. Swizzle steps in to explain that the second iteration requires addressing the same issues again, but in greater depth. The corner icon is brought center screen, a second concentric circle widens around the first to indicate the second iteration, and then it returns to the corner position.

Beginning in the Clinical sector again, Sammy appears before the patient and the nurse, this time with Amy at his side taking notes. After presenting the prototype, the patient responds with concern regarding its size, and the nurse responds that it's too annoying. This interaction fills the second iteration of the Clinical sector in the corner icon. Moving into the Commercial sector, the hospital executive replaces the patient and nurse. He expresses the that current prototype still seems too expensive to be worth any investments. This completes the second iteration of the Commercial sector. Sammy and Amy then appear before the whiteboard again, incorporating the feedback from these two interactions in order to improve their prototype. Their updated solution involves exchanging the alarm for a cellphone, and slimming down the pressure sensing patch. With this update, the second Technical sector is filled. A quick

transition shows them receiving a grant for their innovative work with a banner in the background reading "Healthcare of the Future." A transition to a website page shows the name of their company (PatchMe) and the addition of team members for marketing and consulting as the second full iteration is completed. A conference call is held with all team members to assess the situation moving forward; thumbs up indicates everyone is on board.

The third iteration is started with the updated prototype, which involves Amy pressing a small thin patch on Sammy's arm which triggers his phone to light up with a "Turn Patient" warning. The patient and nurse are both excited about the new iteration. The third Clinical sector is filled. The executive appears again, and this time sees the potential financial benefit of their product. A handshake is exchanged between the executive and Sammy, and the third iteration of the Commercial sector is completed, as the camera slowly pans away. Sammy and Amy are briefly shown moving into the next sector before fading out.

The corner icon is brought back into the center, and narration describes the future considerations for further iterations. These considerations include intellectual property, funding, clinical evaluation, and FDA approval. Visuals appear on top of each sector to accompany the narration, along with definition boxes for intellectual property and the FDA. The visuals fade out as narration reinforces the concept of addressing issues in all sectors in an iterative fashion. Specific issues appear alongside each sector, and the name of the model is described as a spiral appears overlaying the concentric circles. A title box appears reading "The Iterative Spiral Model of Healthcare Innovation." Ms. Swizzle steps in again to describe the future trials and tribulations of such an industry, but the hope for success if the foundation is built properly using this model.

She turns her head towards the spiral and fades out as the spiral tilts away from the screen and becomes the top of a building with the company name "PatchMe Inc." displayed on the front. Sammy, Amy, the patient, the nurse, the hospital executive, and the rest of their team are shown standing before the building, confident and successful. A snapshot is taken and they are all smiling out of the front page of a newspaper as the narration concludes. The headline reads "National Reduction in Pressure Sores!" and the credits begin to roll as part of the newspaper article.

Animatic Feedback Survey

Although it displayed very basic animation and slower pacing, the overall response to the animatic was very positive. Several individuals insisted that it could be used as a final version, if necessary. Informal feedback surveys were sent to a total of ten individuals, six of whom responded with completed documents. These individuals ranged ranged from 24-30 years of age, had either medical or engineering backgrounds, and little to no experience in healthcare innovation. Several responses were given regarding slightly confusing visuals. With regards to the general message, the response was that it was very clear and enjoyable to follow. Comments of note included the following (complete responses can be found in Appendix D):

- "The recurring characters and symbols, as well as the tracking chart in the bottom left, were especially helpful [for following the process]."
- "I was rooting for the main character's design to succeed! I think I felt some genuine happiness and relief when the hospital administrator started seeing the benefit of the product."
- "It was so easy to understand… I hadn't heard of this particular process of innovation/ development and now I feel like I could explain it to someone else."
- "I never thought about the bigger picture of medical device development and this helped break it down."
- "This cartoon-like style livens up what could have been a boring animation. The subject material is dry, but the animation kept me engaged."
- "The main weaknesses I saw pertained to the background and context of the beginning. However, this did not detract from the overall communication of the necessity and basic mechanism of the Iterative Cycle."

Final Animation

The final animation runs just under 6 minutes. Cleaned up assets were used in addition to a professional voice over audio file for narration. Overall, the overall quality was higher and subtler compared to the animatic. Sound effects and background music were also incorporated, which aided flow and engagement throughout the video. The script did not change between the animatic and the final animation. Feedback from the surveys was incorporated primarily through visual additions and changes. One change included developing a more engaging title card. The words "Effective Healthcare Innovation Using an Iterative Method" slide into place, after which "an introduction" appears in handwritten script.

Additionally, during the animatic, several viewers remarked the confusing transition of Sammy's initial idea of solving pressure sores with pillows. To mediate this, thought bubbles were included in the scene where Sammy is thinking up a solution, showing the pressure sore spots mentioned by the patient being covered by pillows. At this point, Sammy transitions to lying on a bed with limbs covered by pillows. The final animation also included didactic spot color for identification and visual clarity. Other small changes were made to aid understanding, and improve pacing. The following figures represent key screenshots from the final animation.

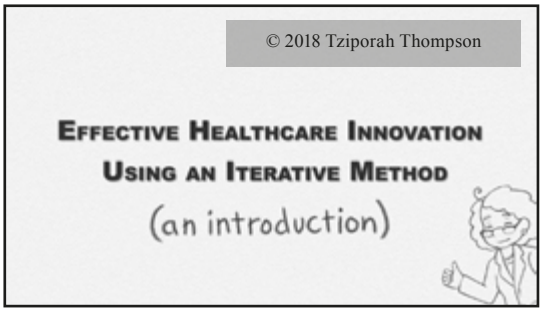


Figure 13. Title Card. Ms. Swizzle peeks in.

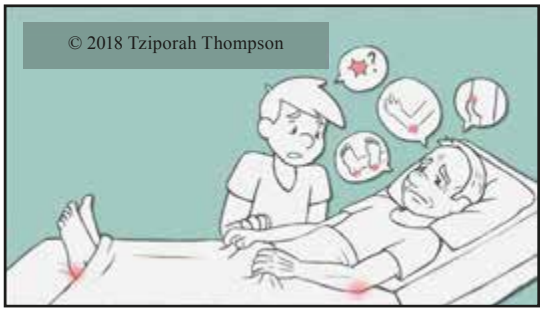


Figure 14. Scene 1. Sammy is introduced as the main character, and pressure sores are introduced as the example clinical problem.

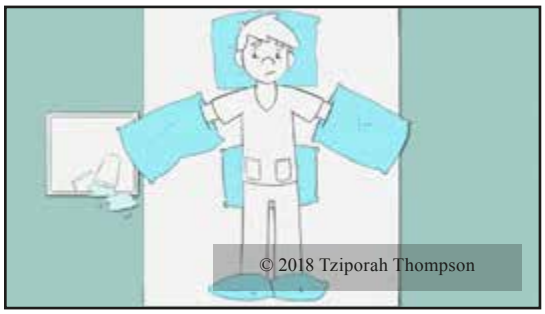


Figure 15. Scene 2. Sammy attempts an initial solution, but fails due to a incomplete understanding of the clinical problem.

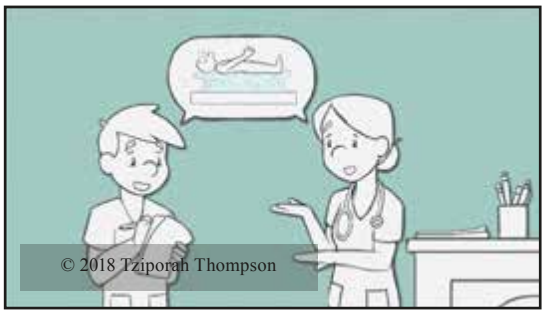


Figure 16. Scene 3. Sammy seeks more information on pressure sores from his resident, and they develop a new solution together.

Figure 17. Scene 4. Sammy meets with a hospital executive who explains that his solution has no commerical benefit.

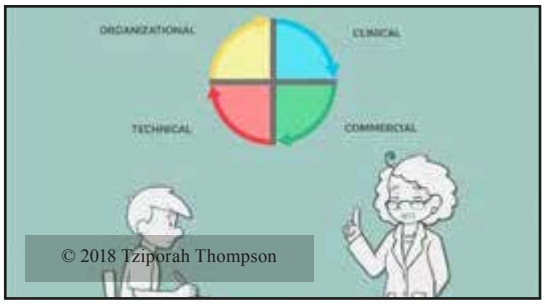


Figure 18. Scene 5. Ms. Swizzle steps in to teach Sammy about the iterative method of approaching healthcare innovation.

Figure 19. Scene 5. Expanded iterative graph

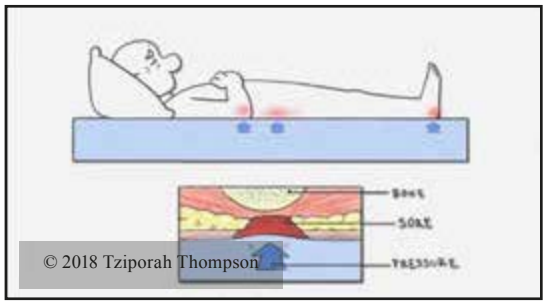


Figure 20. Scene 6. Graphic explaining the mechanics of pressure sores.

Figure 21. Scene 7. Sammy seeks stakeholder feedback in the clinical sector by speaking to the patient and the nurse.

Figure 22. Scene 8. Sammy performs preliminary market research to assist product design and development.

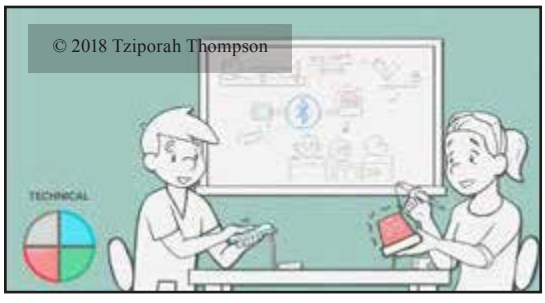


Figure 23. Scene 9. Amy the engineer is introduced to help Sammy build a prototype.

Figure 24. Scene 11. Clinical feedback, second iteration.

Figure 25. Scene 12. Funding recieved, second iteration of the Organizational sector.

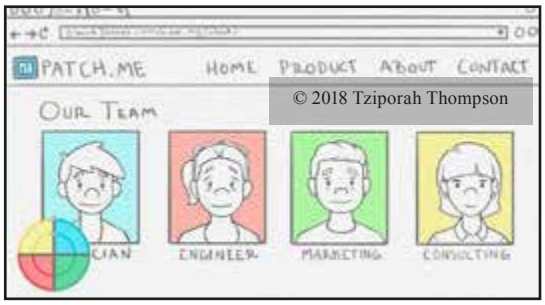


Figure 26. Scene 12. Completed second iteration, growing team and company.

Figure 27. Scene 12. Collective team agreement on product advancement.

Figure 28. Scene 14. Future considerations. Text not intended to be read.

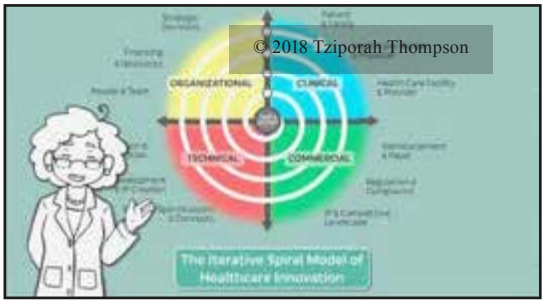


Figure 29. Scene 14. Ms. Swizzle presenting the full spiral model. Text not intended to be read.

Figure 30. Scene 15. Final shot of happy stakeholders.

Access to Assets

The animatic and final animation of this thesis can be found at tziporahthompson.com or their original URLs (animatic: https://youtu.be/IHNkQun2lMg and final animation: https://vimeo.com/260345692). The author can be contacted through the Department of Art as Applied to Medicine at Johns Hopkins University School of Medicine, http://medicalart.johnshopkins.edu/

Discussion

Survey Responses

This project consisted of several rounds of informal feedback via survey. Similar to the paradigm of the project content itself, these surveys sought stakeholder feedback at key points in each iteration of development. The initial content expert interviews provided perspective for the inherent variability of successfully navigating the industry of MedTech. This understanding was important for developing learning objectives and shaping the overall delivery of the animation. The animatic feedback survey provided validation that the narrative storyline was successful in breaking down the core concept of the iterative model and conveying its application in a clinical setting. It also brought to light weak aspects of the visual narrative, which could be easily addressed before starting development of the final animation. Currently, we are in the process of applying for IRB approval in order to conduct a formal pre-post survey of the educational efficacy of the final animation. We are hopeful that this data will provide further insight into educating new innovators in successful MedTech navigation.

Stylistic Choice

The format of this animation was initially inspired by the Schoolhouse Rock! educational videos. While brainstorming the style and visual quality, inspiration was drawn from the traditional animations of Walt Disney and Hayao Miyazaki, and the style of Bill Watterson's comics. The initial intention was to create a full traditionally animated narrative. However, due to time constraints, this became an unrealistic objective. Though interpolation animation was ultimately used, a traditional visual quality was maintained, and traditional animation principles were acknowledged. This was shown through the use of the pencil-line quality of the final assets, the paper texture of the final animation, the drop-shadow effect on the characters, and squash-and-stretch techniques for the character movement.

Animation Software

The choice of animation software required a comprehensive review of several available programs. Initial considerations included apparent learning curve, cost, brush options and traditional animation capabilities. One important capability considered was onion-skinning. This is a technique which involves layering frames or images to discern the subtle changes between each drawing over time. For this form of

animation, TVPaint is considered one of the industry standards. Its user interface is designed specifically for traditional animators, creating an intuitive and efficient workflow for frame-by-frame animation. TVPaint also provides beautifully textured and pressure sensitive brushes for sketching and coloring. Onion-skin controls include up to ten frames of visibility before and after the active frame, as well as opacity levels for each skin. Due to its traditional basis, TVPaint has no vector animation or interpolation capabilities. It is also quite expensive to purchase the full professional program (TVPaint, 2018). Ultimately, a trial version of TVPaint was used only for animating select frame-by-frame sequences of lip-syncing for Ms. Swizzle's narration.

Alternatives for onion-skinning capabilities include ToonBoom, Adobe® Animate® and Photoshop. ToonBoom is available in three tiers of monthly price points, each with a higher level of capability. It is also known to have a much steeper learning curve (Bloop Animation, 2018). ToonBoom is mainly comprised of vector based drawing tools, but a monthly subscription to the second tier offers bitmap drawing and more robust painting tools. Although this program is considered an industry standard for 2D animation, due to time and funding constraints, it was not used. Animate also offers vector based drawing, however with limited options for brush variability. The default brush has no texturing, resulting in a very smooth, and mostly uniform line. Animate's timeline and onion-skinning are very straight forward and intuitive, especially for those familiar with the Adobe interface. Due to its availability along with the Adobe CC Suite subscription provided by this graduate program, cost was not prohibitive. Lastly, Photoshop has a timeline feature which includes onion-skinning. Though not intuitive, it provides a much easier option than pursuing an entirely new program. The main issue with this Photoshop feature is that when turned on, onion-skinning requires a baffling amount of RAM, resulting in lag that renders the entire feature virtually useless on device akin to a MacBook Pro.

Ultimately, After Effects was primarily used for its ability to easily interpolate and transform layers, and traditional animation techniques were deprioritized. Additionally, assets made in Photoshop and Illustrator were able to link directly into After Effects, making it very easy to edit assets during the animation process. Efficiency of time and lack of additional cost proved to be the highest priority in this project's lifeline.

Choosing an Example Clinical Problem

Several group discussions were initiated before an appropriate clinical problem was decided upon to carry the narrative of the animation. Initially, we postulated using a wheelchair bound child, for whom the main character attempted to develop a series of robotic legs. This scenario had potential for humor, and flexible product portrayals, but ultimately it was decided that the sensitivity of the subject matter could distract from conveying the iterative process. Pressure ulcers were considered as an alternative.

Pressure ulcers most often occur in senior patients when poor circulation and prolonged pressure on bony prominences result in a necrosis of the overlying tissue. Current clinical solutions include gel topped mattresses, large gel-based bandages, and even air-jet equipped beds. The best clinical solution is still frequent rotation of patients in order to reduce pressure in one area over time, but this technique is extremely prone to human error and neglect. Furthermore, patient insurance policies often do not cover costs associated with the treatment of pressure ulcers, which results in a significant financial burden for the hospital and healthcare industry as a whole. It has been estimated that the associated costs of pressure ulcers in the US is $9.1-$11.6 billion annually (AHRQ, 2014).

Thus, pressure ulcers were chosen as a clinical example due to their prevalence, technical simplicity, and real-world economic burden. As for depicting a clinical solution to this problem, we were able to reference a project actively being developed by Dr. Justin Sacks at Johns Hopkins School of Medicine. His team is creating pressure sensitive patches which use Bluetooth technology to alert nursing staff before dangerous levels of pressure are exerted on the tissue overlying a patient's bony anatomy, thus preventing the development of a pressure ulcer. This example solution provided a believable, real-world scenario with enough technical simplicity for ease of storytelling without distraction from the main message.

Character Diversity

During the planning phases of storyboarding and character development, thought was given to visually representing diversity of race and gender. Though cartoon characters were used, it is important that the viewers of this animation see themselves reflected in the narrative. Due to time constraints, a stylistic choice was made in order to have a complete animation: the majority of the animation was left without any value or color, except for didactic color for visual clarity. Future iterations of the animation hope to have fully colored characters, with clear diversity.

Figure 31. Character color composition

Animation Efficiency

The finished look of the final animation was satisfactorily in-line with the originally proposed conception. However, due to the mid-project pivot from attempting a fully traditional animation, to relying heavily on interpolation based animation, a workflow was generated that though successful, may not have been the most time efficient method. The need to create a new Photoshop layer for every change in character position necessitated an intense level of organization and consistency, in which a total of 563 visual assets were managed throughout the course of the animation (not including duplicated or new assets created in After Effects). An alternative method of character animation using the interpolation capabilities of After Effects would have been to rig individual body parts for joint control. This would have generated far fewer assets, and allowed for a higher level of character mobility. However, the highly simplistic shapes used in popular After Effects rigging models does not support as much variability in visual appeal, or anatomical realism. The benefit of individual Photoshop layers as assets is the inherent creative freedom. Thus, the method used for this project was ultimately successful in its final visualizations, and an extremely important learning experience for workflow planning and management.

Future directions

An IRB protocol has been submitted in order to conduct a pre-post test regarding the efficacy of the animation as a learning tool. Furthermore, while animation provides an excellent vessel for imparting information, it is inherently a passive learning process. In order to supplement the introductory animation

with an active learning component, future directions for this project include creating an interactive web-based module for a detailed breakdown of the iterative spiral model. This would provide users an obvious "next step" in the learning process, after viewing the animation, in addition to more detailed definitions and vocabulary. The animation and interactive would be hosted on a webpage through CBID. This webpage would provide further resources for users to explore, including case studies and testimonials of experienced MedTech innovators.

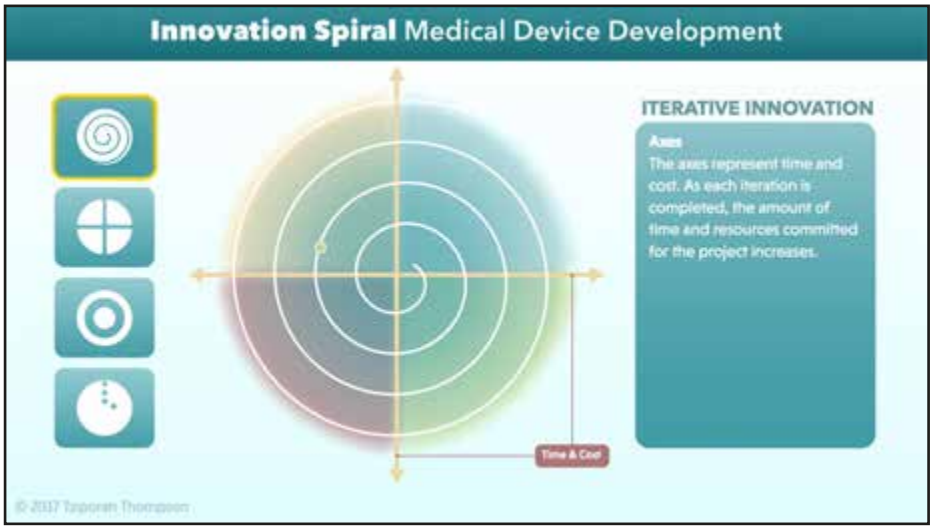


Figure 32. Interactive mockup 1. Text not intended to be read.

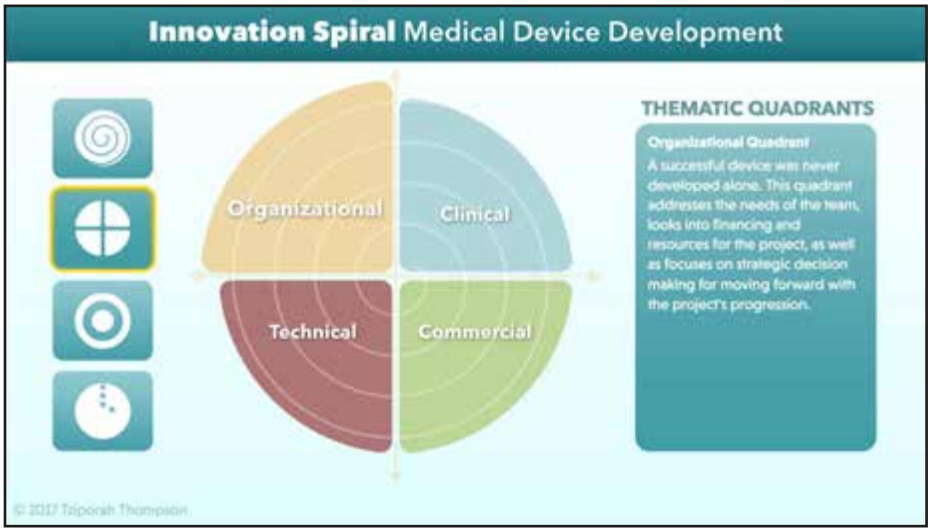


Figure 33. Interactive mockup 2. Text not intended to be read.

Conclusion

With new technologies being rapidly developed every day, it is important that effective resources exist for the next generation of innovators to successfully navigate their development process. This is especially significant in healthcare, due to the fact that innovations in this industry are directly correlated with the progressive health of the global community. Today's generation has the privilege of access to an unparalleled wealth of information via the internet. However, seeking direction through online resources can easily be overwhelming to any first-time entrepreneur or engineer looking to develop an idea.

The result of this project was an engaging animation for communicating the importance of approaching healthcare innovation in an iterative fashion. Though visually appealing, the most important aspect of this project was the clarity of communication. A masterfully rendered medical illustration is educationally useless without a visual story or clear hierarchy of information. By giving extreme care and attention to the development of the script, our team was able to create a narrative which not only successfully educated viewers, but kept them engaged, even when rough storyboards were the only visuals. It is our hope that this animation, along with the planned interactive and resource rich webpage, will provide the next generation of movers with a launch pad to confidently move forward in their innovation process.

APPENDICES

Appendix A: Content Expert Surveys

Dr. Ashish Nimgaonkar Interview, page 1

Date: 8/30/17

Name: Ashish Nimgaonkar

Company/Product:

Can I record this conversation?

BACKGROUND:

Tell me a little about your product.

When was it initiated? Why?

What was your inspiration?

Who else did you work with?

What was the problem you were addressing? How did you identify it?

What was your proposed solution?

Does your current product still reflect that?

Can you speak about that evolution?

What is the current status of your product?

COMMERCIAL:

What was the space like when you started?

Were there competitors? How did you compare, where did you fit?

What were your primary sources of funding throughout the process?

Dr. Ashish Nimgaonkar Interview, page 2

Who are the purchasers, and how many have you had?

Who was your biggest non-monetary support?

Did you disclose? When?

DEVELOPMENT:

How much did you know about the development process when you started?

Do you know of the iterative innovation spiral? Did it help?

What do you wish you had known?

Did you have any guidance or role model?

What was your biggest setback? (regulatory, financial, technical)

What was your biggest breakthrough?

What was your physical product development process? Did you work with anyone?

What was your minimally viable product?

What surprised you the most?

CLOSING:

Was it worth it?

Did you ultimately spend more time or more money on your product?

May I contact you again if I have further questions?

Dr. Hien Nguyen Interview, page 1

Date: 9/7/14

Name: Dr. Hien Nguyen

Company/Product: ____

Can I record this conversation?

BACKGROUND:

Tell me a little about your product.

When was it initiated? Why?

2012

What was your inspiration?

Who else did you work with?

What was the problem you were addressing? How did you identify it?

What was your proposed solution?

Does your current product still reflect that?

Can you speak about that evolution?

What is the current status of your product?

COMMERCIAL:

What was the space like when you started?

Were there competitors? How did you compare, where did you fit?

What were your primary sources of funding throughout the process?

Dr. Hien Nguyen Interview, page 2

Who are the purchasers, and how many have you had?

Who was your biggest non-monetary support?

Did you disclose? When?

DEVELOPMENT:

How much did you know about the development process when you started?

Do you know of the iterative innovation spiral? Did it help?

What do you wish you had known?

Did you have any guidance or role model?

What was your biggest setback? (regulatory, financial, technical)

What was your biggest breakthrough?

What was your physical product development process? Did you work with anyone?

What was your minimally viable product?

What surprised you the most?

CLOSING:

Was it worth it?

Did you ultimately spend more time or more money on your product?

May I contact you again if I have further questions?

Appendix B: Animation Script

(Numbering system used to associate storyboards)

(1) So - you're a medical student. (2) Say - third year.

(3) Your hospital is short staffed, and pressure sores are popping up everywhere.

(4) The patients are unhappy, (5) the nurses are at their limit, (6) and it's costing the hospital thousands of dollars. (7) There has to be a better way. (8) You think you can solve this problem.

(9) Pressure sores might go down, but there are other problems... (10) Scratch that.

(11) This time - you try getting advice from your resident. (12) Now you're both excited.

(13) But - solving this problem is more complicated than you expected, so you book a meeting with a financial executive at the hospital, hoping for more support.

(14) You explain your solution, but he's not quite convinced. (15) He says pressure sores are already expensive enough, and your solution wouldn't save him any money.

(16) So, now what? (17) Don't worry, I'm here with a strategy to help you navigate your problem solving process. (17.5) You've discovered that problem-solving in the medical field is more complicated than you expected. (17.6) First, let's organize these issues into four main categories: Clinical, Commercial, Technical, and Organizational. (18) We call these "sectors." You cannot address everything at once, so it's important to take an iterative approach.

(19) "Iterative" means that you build your understanding and solution gradually, over time, using feedback from stakeholders. That way you don't miss anything!

(20) It's always best to start in the Clinical sector.

(21) You're trying to solve an existing medical problem: pressure sores can be prevented by frequent patient rotation. But if neglected, they can become dangerous and difficult to treat.

(22) So what's your angle? Treatment? Prevention?

(23) To better understand the problem, you hear from the patient (24) and then you hear from the nursing staff… (25) Now you're on to something!

(26) But before you get too excited, consider all of the issues in the Commercial sector.

(27) Remember, you need to think about the cost to the hospital and the patient! Who's going to pay for this? (27.5) And what's already available in the market? How well does it work? How should your innovation be better?

(28) Your design will be shaped by understanding how current products fail to fully solve the problem.

(29) Now - you have an idea, and you recognize the gaps in the market. Time to build something! That's in the Technical sector. (30) You call an engineering friend to help construct a product based on your idea. (31) Together, you sketch out concepts, work through some technical problems, and come up with a rough prototype. (32) Nice work! You've started to build your team. This is an important part of the Organizational sector.You'll need to strategize about your plans moving forward, and start thinking about funding for your project.

(33) You've done a great job addressing issues in each sector! It's time to pause and take stock; do you feel you have a better solution, overall? Yes! Everything looks good!

(34) This is just the beginning. For your next iteration, you'll address the issues in each sector again, but now in greater depth. (35) As before, you start by seeking Clinical feedback. (36) The patient says it's too big, and the nurse says it's too annoying.

(37) Turning to Commercial issues, the hospital exec says it still seems too expensive.

(38) As for the Technical issues: This feedback means you're able to move forward and improve your prototype. (39) Lastly, Organizational issues: Your working prototype and supporting research makes finding funding a little bit easier. (40) Your team is bigger, and you've taken another turn through each sector. Now take stock again. Does your plan still make sense? Is the whole team on board for the next iteration? Great! (42) Here we go again! The patient is comfortable, and the nurse approves! (43) The hospital - is beginning to see how your product can save money.

(44) You're off to a great start! But there's still a long way to go.

(45) Some of the steps ahead include seeking further advice on: intellectual property; funding; clinical evaluation; and FDA approval.

(46) Just remember to continue working through all the issues, and neglecting none by following the iterative model.

(47) This development path is called the "Iterative Spiral Model of Healthcare Innovation."

(48) There will be many obstacles, but the potential strength of your project will increase as you gradually and equally iterate through each sector.

(49) With time, use of this model - and hard work - you can address all issues and navigate toward success.

Appendix C: Storyboards

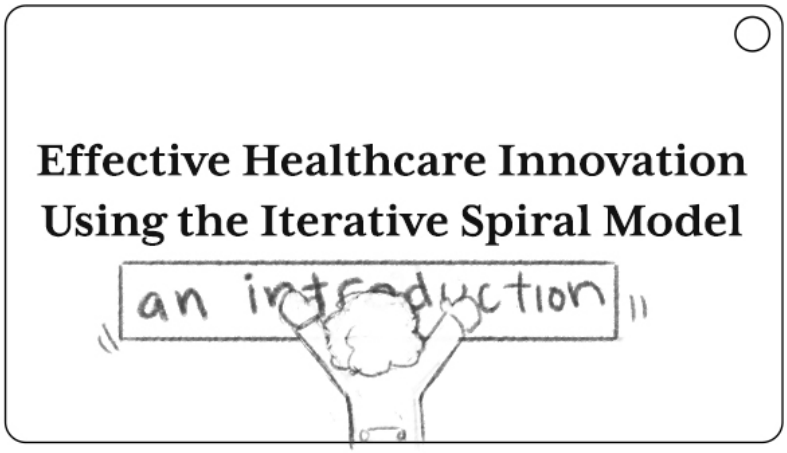
Project: Thesis Title Sequence: Date: 1/24/18 Client: Page:

Video: title slams into place one word at a time

Audio:

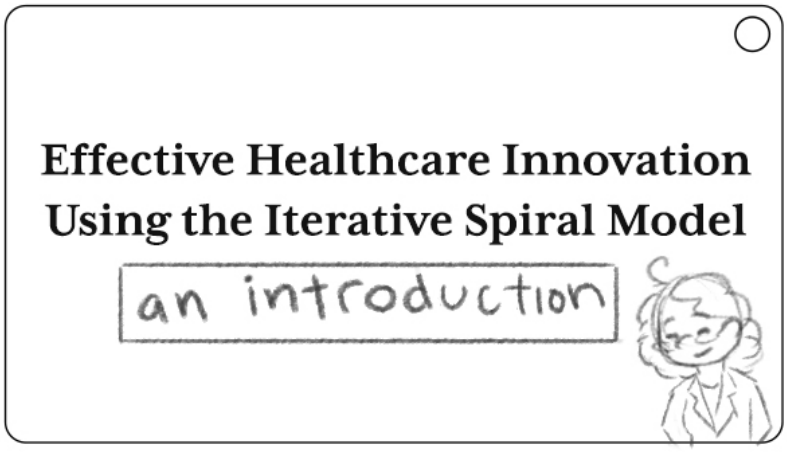
Video: Mentor walks on with sign

Audio:



Video: Mentor steps off to the side

Audio:



Project: Spiral Animation Sequence: 1-3 Date: 12/1/17 Client: BME Dept Page: 1

1.
Video:
Audio:
So, you're a medical student.
[SFX: pop!]

2.
Video:
Audio:
Say, third year.
[SFX: phew!]

3.
Video:
Audio:
Your hospital is short staffed, and pressure soures are popping up everywhere.
[SFX: pop-gasp-weee]

Project: Spiral Animation Sequence: 4-6 Date: 12/1/17 Client: BME Dept Pgs: 2

4.
Video:
Audio:
The patients are unhappy...
[SFX: pop-pop-pop]

5.
Video:
Audio:
The nurses are at their limit...
[SFX: footfalls-impact]

6.
Video:
Audio:
-and it's costing the hospital thousands of dollars.
[SFX: poof]

Project: Spiral Animation Sequence: 7-8a Date: 12/6/17 Client: BME Dept Page: 3

7a.
Video:
Audio:
There has to be a better way.
[SFX:]

7b.
Video:
Audio:
You think you can solve this problem.
[SFX: ding!]

8.
Video:
Audio:
[SFX:]

Project: Spiral Animation Sequence: 8b-8d Date: 12/6/17 Client: BME dept Page: 4

9a.
Video:
Audio:
Pressure sores might go down...
[SFX: poof]

9b.
Video:
Audio:
-but there are other problems..
[SFX: wiggle-splash]

10.
Video:
Audio:
Scratch that.
[SFX: poof]

Note: page 5 of story boards was editted out.

ject: Spiral Animation Sequence: 11-12 Date: 12/6/17 Client: BME Dept Page: 6

11a.
Video:
Audio:
This time-
[SFX: pop-pop-pop]

11b.
Video:
Audio:
-you work with feedback from your resident.
[SFX:]

12.
Video:
Audio:
Now you're both excited.
[SFX: air hiss]

Project Sequence: 13 Date: Client: Page: 7

13a.
Video:
Audio:
But solving this problem is more complicated than you expected.
[SFX: pop]

13b.
Video:
Audio:
So you book a meeting with a financial executive at the hospital-
[SFX: pop]

13c.
Video:
Audio:
-hoping for more support.
[SFX: crash!]

Project Sequence 14 Date Client Page 8

14a.
Video:
Audio:
You explain your solution-
[SFX: door open]

14b.
Video:
Audio:
-but-
[SFX: snatch]

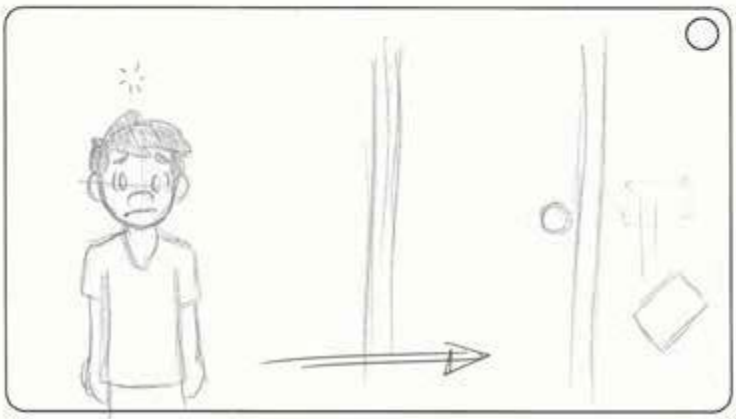
14c.
Video:
Audio:
-he's not quite convinced.
[SFX:]

Project Sequence 15-16 Date Client Page 9

15a.
Video:
Audio:
He says pressure sores are already expensive enough and your solution wouldn't save him any money.
[SFX: pop-pop-pop]

15b.
Video:
Audio:
[SFX: slam! rustle-tinkle]

16.
Video:
Audio:
So, now what?
[SFX:]



Project Sequence 17 Date Client Page 10

17a.
Video:
Audio:
Don't worry,
[SFX: ding!]

17b.
Video:
Audio:
I'm here with a strategy to help you navigate your problem solving process.
[SFX: piff]

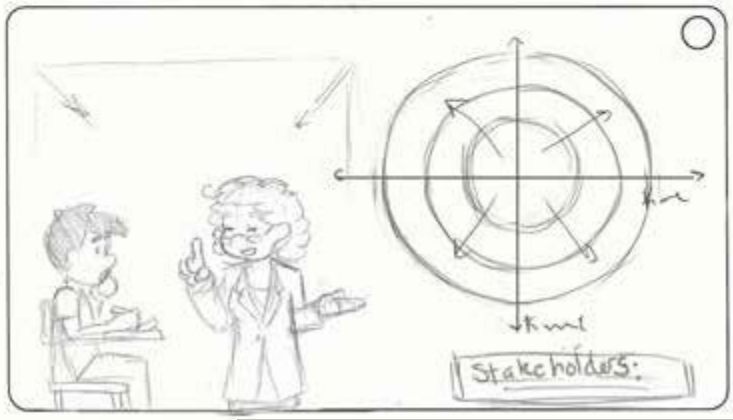
17.5.
Video:
Audio:
You've discovered that problem-solving in the medical field is more complicated than you expected.
[SFX: pops in appearance]

Project Sequence 17.5-19 Date Client Page 11

17.6.
Video:
Audio:
First, let's organize these issues into four main categories: Clinical, Commercial, Technical, and Organizational.
[SFX: dings in sync]

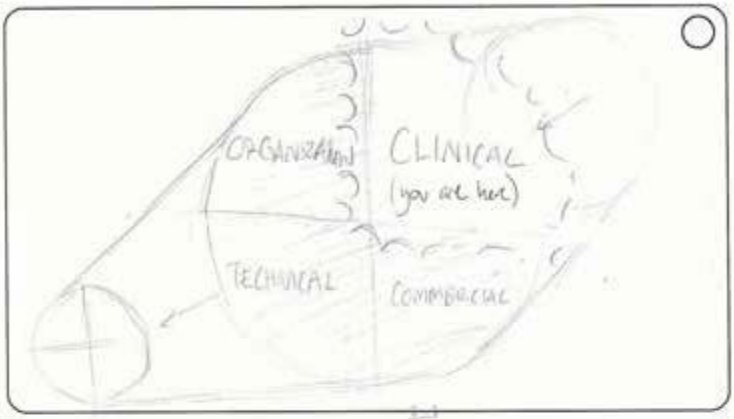
18.
Video:
Audio:
We call these "sectors." You cannot address everything at once, so it's important to take an iterative approach.
[SFX: click]

19.
Video:
Audio:
"Iterative" means that you build your understanding and solution gradually, over time, using feedback from stakeholders. That way you don't miss anything!
[SFX:]

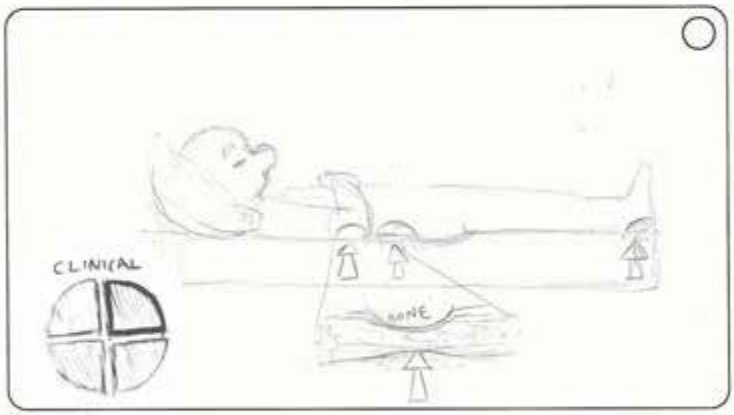


Project Sequence 2-2-16 Date Client Page 12

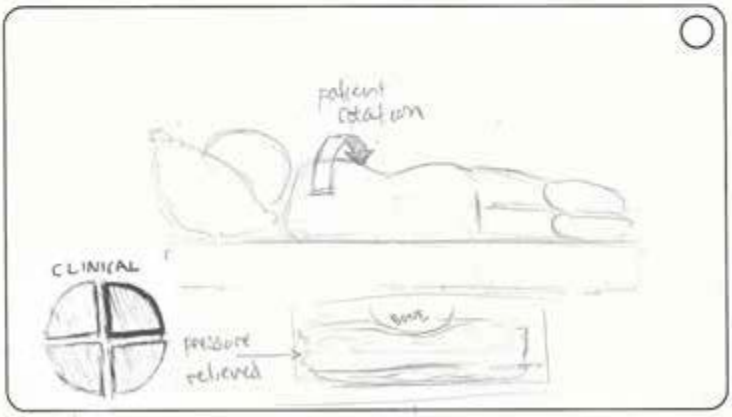
20.
Video:
Audio:
It's always best to start in the Clinical sector.
[SFX:]



21a.
Video:
Audio:
You're trying to solve an existing medical problem.
[SFX: wum-wum-wum]

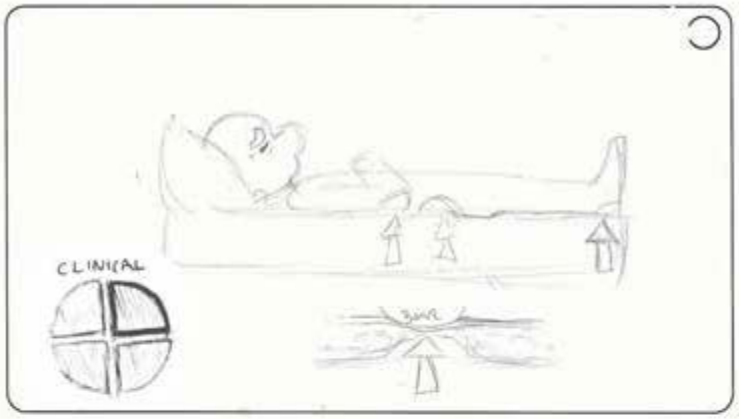


21b.
Video:
Audio:
Pressure sores can be prevented by frequent patient rotation.
[SFX:]



Project Sequence 21c-23 Date Client Pg: 13

21c.
Video:
Audio:
But if neglected, they can become dangerous and difficult to treat.
[SFX: louder wums]



22.
Video:
Audio:
So what's your angle? Treatment? Prevention?
[SFX:]

23.
Video:
Audio:
To better understand the problem, you hear from the patient...
[SFX: writing]

Project Sequence 24-26 Date Client Page 14

24.
Video:
Audio:
..and then you hear from the nursing staff.
[SFX: writing]

25.
Video:
Audio:
Now you're on to something!
[SFX: ding!]

26.
Video:
Audio:
But before you get too excited, consider issues in the Commercial sector.
[SFX: poof]

Project Sequence 27-28 Date Client Page 15

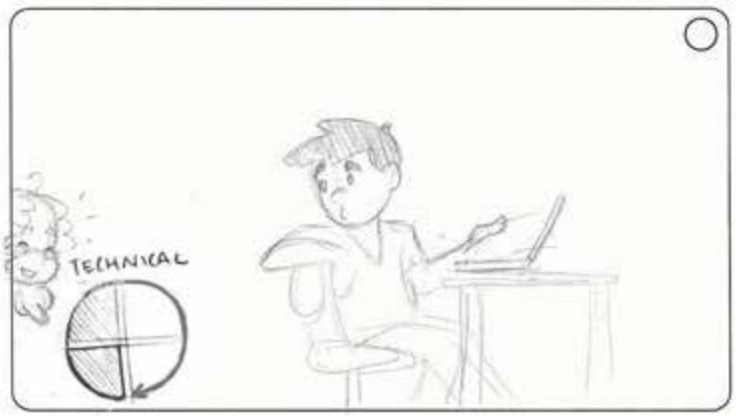
27.
Video:
Audio:
Remember, you have to think about the cost to the hospital and the patient. Who's going to pay for this?
[SFX: poof]

27.5.
Video:
Audio:
And what's already available in the market? How well does it work? How should your innovation be better?
[SFX: typing]

28.
Video:
Audio:
Your design will be shaped by understanding how current products fail to fully solve the problem.
[SFX:]

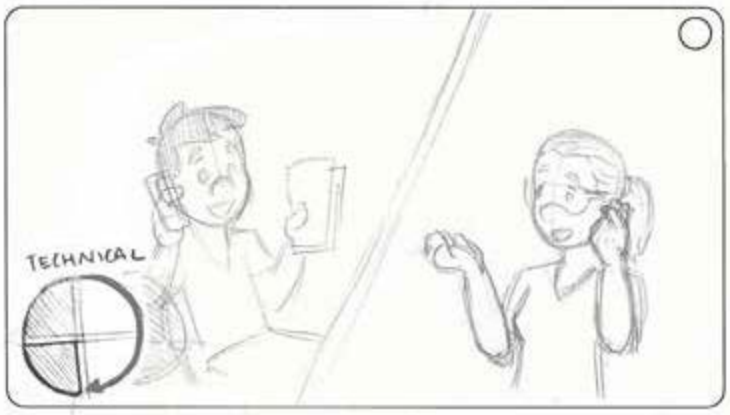
Project Sequence 29-30 Date Client Page 16

29.
Video:
Audio:
Now, you have an idea, and you recognize the gaps in the market. Time to build something! That's in the Technical sector.
[SFX:]



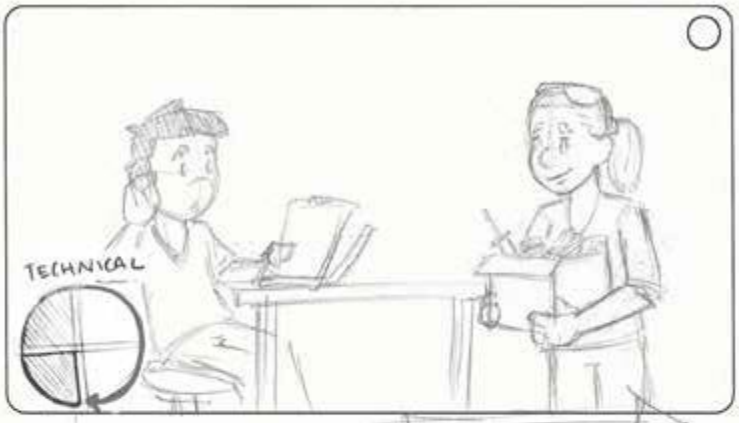
30a.
Video:
Audio:
You call an engineering friend...
[SFX:]

30b.
Video:
Audio:
...to help construct a product based on your idea.
[SFX:]

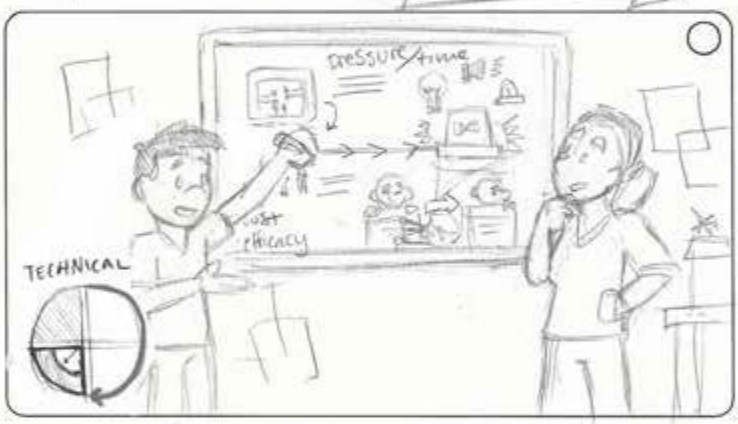


Project Sequence Date 3|a-3|c Client Page 17

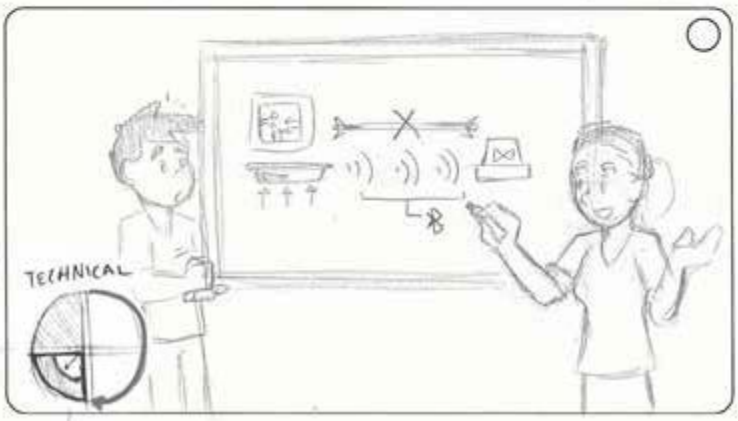
31a.
Video:
Audio:
Together...
[SFX:]



31b.
Video:
Audio:
You sketch out concepts...
[SFX:]



31c.
Video:
Audio:
Work through some technical problems...
[SFX:]

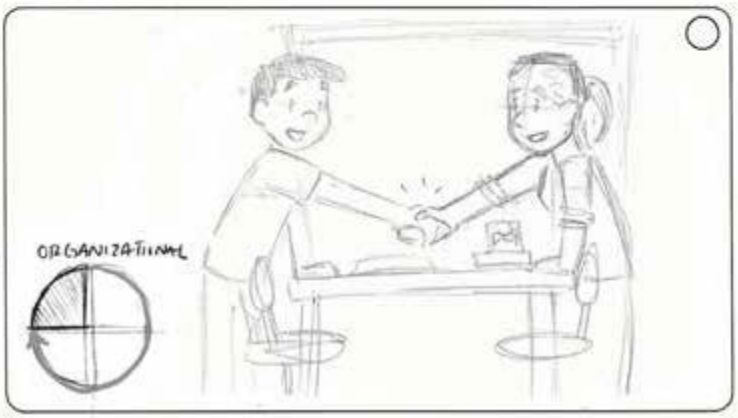


Project: Sequence: Date: 31d-32a Client: Page: 18

31d.
Video:
Audio:
And come up with a rough prototype.
[SFX:]

32a.
Video:
Audio:
Nice work!
[SFX: alarm sound]

32b.
Video:
Audio:
You've started to build your team. This is an important part of the Organizational sector.
[SFX: ding!]



Project: Sequence: 32c-33b Date: Client: Page: 19

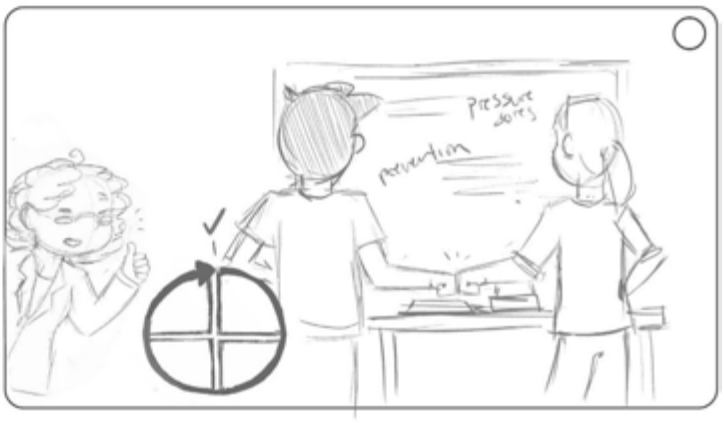
32c.
Video:
Audio:
You'll need to strategize about your plans moving forward, and start thinking about funding for your project.
[SFX:]

33a.
Video:
Audio:
You've done a great job addressing issues in each sector! It's time to pause and take stock;
[SFX:]

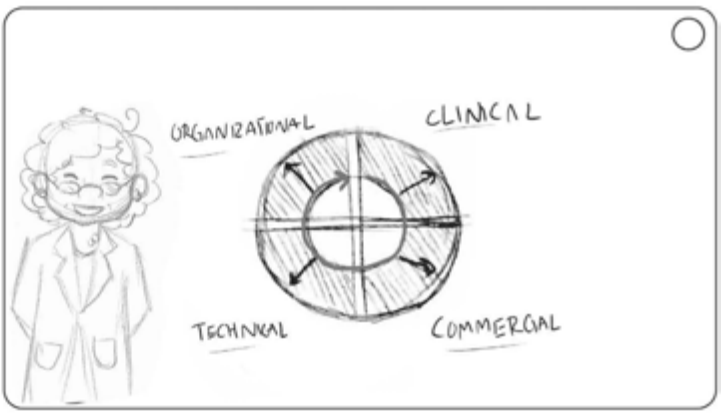
33b.
Video:
Audio:
Do you feel you have a better solution, overall?
[SFX:]

Project: Sequence: 33c-35 Date: Client: Page: 19.5

33c.
Video:
Audio:
Yes! Everything looks good!
[SFX: bam!]



34.
Video:
Audio:
This is just the beginning. For your next iteration, you'll need to address the issues in each sector again, but now in greater depth.
[SFX:]



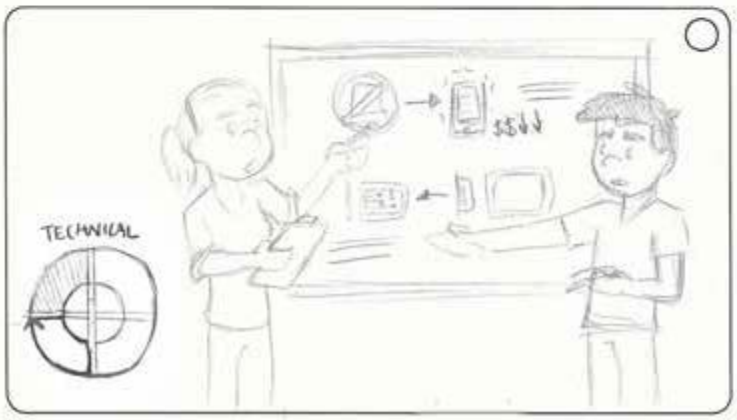
35.
Video:
Audio:
As before, you start by seeking Clinical feedback.
[SFX:]

Project Sequence: 36-38 Date: Client Page: 20

36.
Video:
Audio:
The patient says it's too big, and the nurse says it's too annoying.
[SFX: alarm sound]

37
Video:
Audio:
Turning to Commercial issues, the hospital exec says it's still seems too expensive.
[SFX:]

38.
Video:
Audio:
As for the Technical issues: This feedback means you're able to move forward and improve your prototype.
[SFX:]



Project Sequence 39-41 Date Client Page 21

39.
Video:
Audio:
Lastly, Organizational issues: Your working prototype and supporting research makes finding funding a little bit easier.
[SFX: cheering]

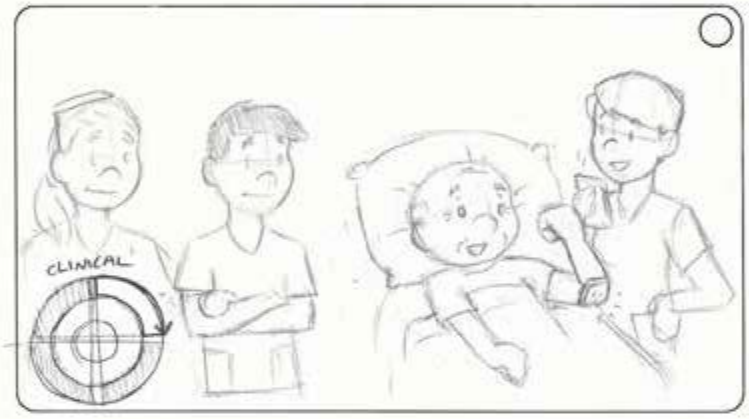
40.
Video:
Audio:
Your team is bigger, and you've taken another turn through each sector.
[SFX:]

41.
Video:
Audio:
Now take stock again. Does your plan still make sense? Is the whole team on board for the next iteration? Great!
[SFX: ding ding ding!]

Project: Sequence: 42 - 43a Date: Client: Page: 22

42a.
Video:
Audio:
Here we go again!
[SFX: beep beep]

42b.
Video:
Audio:
The patient is comfortable and the nurse approves!
[SFX:]

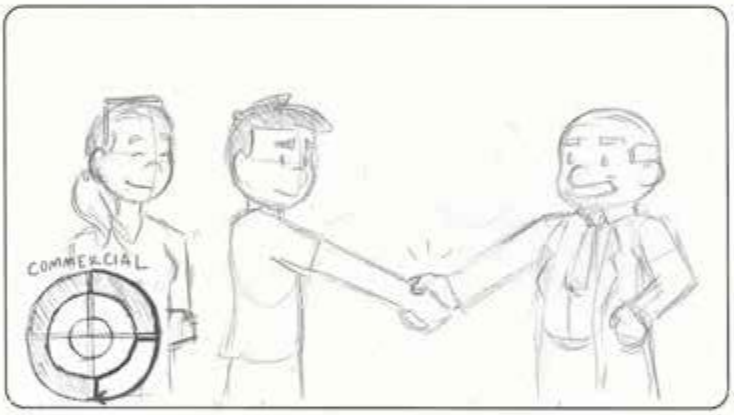


43a.
Video:
Audio:
The hospital exec...
[SFX:]

Project Sequence 43-44 Date Client Page 23

43b.
Video:
Audio:
..is beginning to see how your product can save money.
[SFX:]

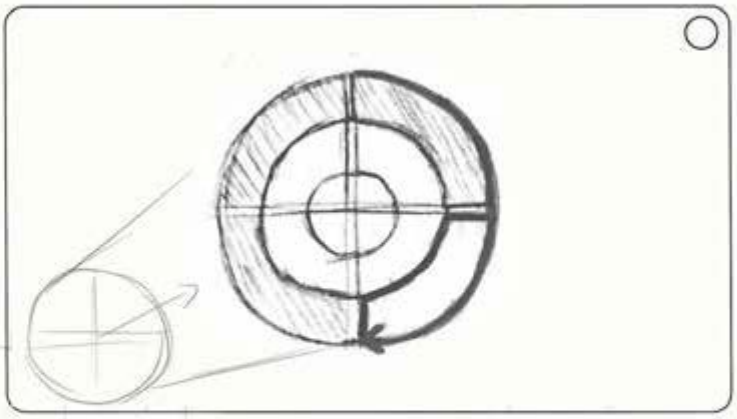
44a.
Video:
Audio:
You're off to a great start!
[SFX:]



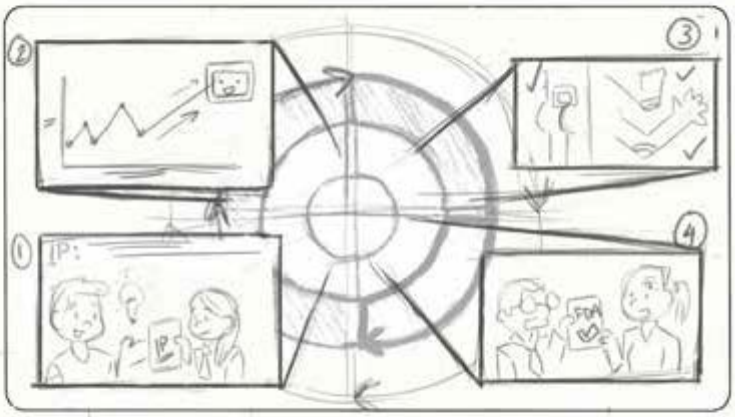
44b.
Video:
Audio:
But there's still a long way to go.
[SFX:]

Project: Sequence: 45-46 Date: Client: Page: 24

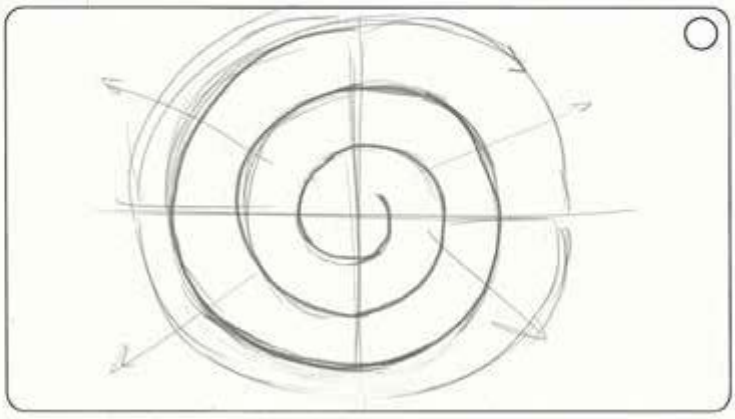
45a.
Video:
Audio:
Some steps ahead include...
[SFX:]



45b.
Video:
Audio:
Seeking further advice on intellectual property(1); funding(2); clinical evaluation(3); and FDA approval(4).
[SFX:]

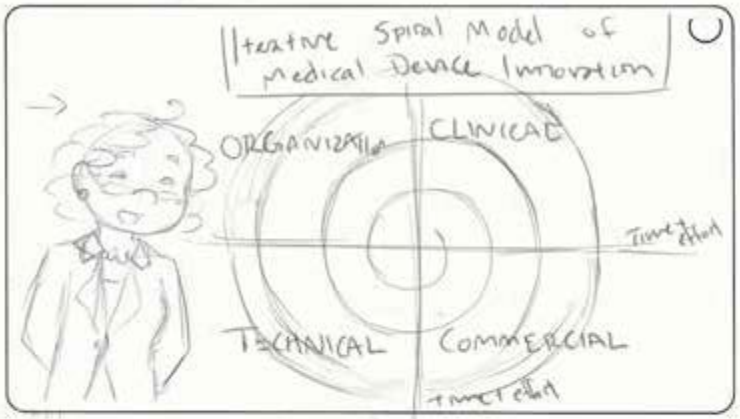


46.
Video:
Audio:
Just remember to continue working through all the issues, and neglecting none by following the iterative model.
[SFX:]

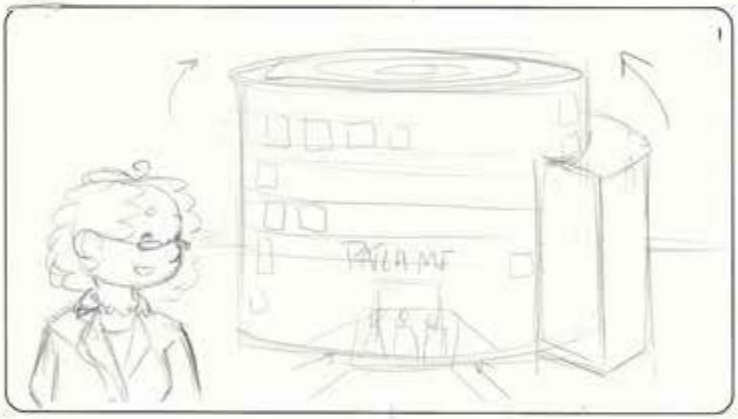


Project: Sequence: 47-49 Date: Client: Page: 25

47.
Video:
Audio:
This development path is called the "Iterative Spiral Model of Health Care Innovation"
[SFX:]



48.
Video:
Audio:
There will be many obstacles but the potential strength of your project will increase as you gradually and equally iterate through each sector. [SFX:]

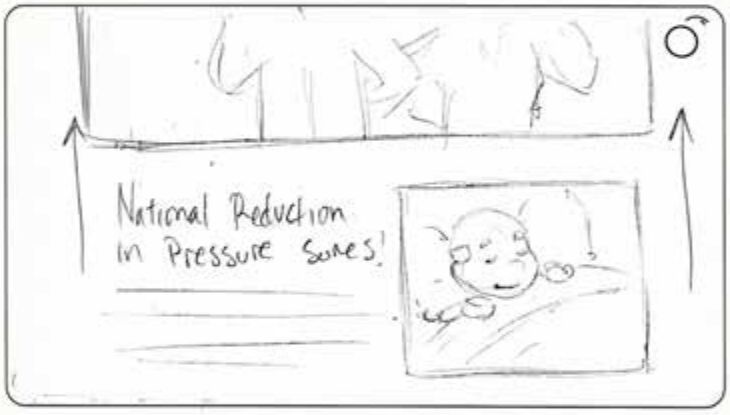


49a.
Video:
Audio:
With time, use of this model and hard work..
[SFX:]

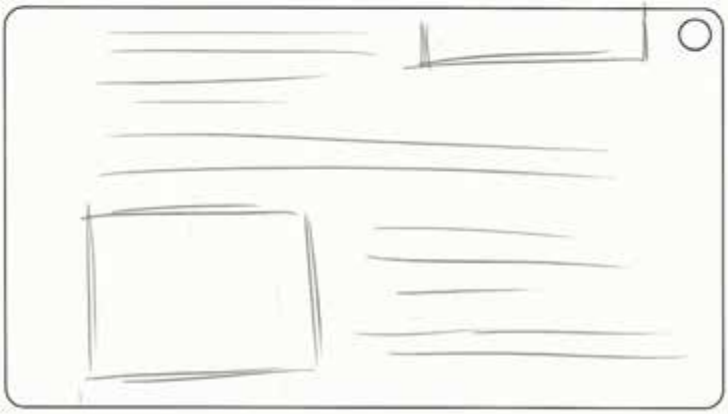
Project Sequence 49b- credits Date Client Page 26

49b.
Video:
Audio:
...you can address all issues and navigate toward success.
[SFX:]

49c.
Video:
Audio:
[SFX:]



Credits
Video:
Audio:
[SFX:]



Appendix D: Animatic Feedback Surveys

1. **Were you able to understand the message of this animation?**

   -Yes

   -Yes

   -Yes, it was very clear and easy to follow. The animation was illustrating the process and benefits of healthcare innovation via the iterative spiral model.

   -By the end everything was very clear. I know the script isn't able to change, but during the first minute spent building up the background story I became excited to learn about pressure sores solutions, but completely forgot what the title and point of the video was. Maybe there is some way to tie the components of the spiral model sectors visually into the trials the med student goes through at the beginning?

   -An iterative cycle is essential to developing a product in a space that has continuous crosstalk between the entities that use/regulate/pay for/benefit from the product.

2. **Did you learn something new?**

   -Yes – this was super interesting!

   -So so. The concept seems to be obvious to anyone who has tried implementing an idea within an organization. This video just further clarified what I've already experienced.

   -Yes. We actually learned a bit about this process in school last year in relation to problem-solving in the healthcare setting. However, I did not fully grasp the concept until watching this animation.

   -Yes, I never thought about the bigger picture of medical device development and this helped break it down. The 4 categories weren't immediately memorized after the first go, though this might come with some additional color coordination and cues for each section.

   -Mainly, some new ways to describe what I've been doing but my background on this significantly colors this element of the feedback.

3. **Was the storyline clear and easy to follow?**

   -Very

   -Yes

   -Yes. I really enjoyed the fact that the storyline centered a 3rd year student. It was fun to watch him progress from naïve (but optimistic) student to leader of a medical device company

   -I liked the recurring characters like the grumpy moustache boss man. Made it easier to see the iterative repeating process. The different steps do have some dissonance in the level of detail given with examples in the script (i.e. first clinical step describes what bed sores are, but "commercial" doesn't have any concrete examples linked back to the story context). Not a huge

problem for me, and will probably be fixed with more elaboration visually in the animation.

-The beginning would be a bit rough without knowing why a person would put pillows on someone's limbs. If someone didn't know what bedsores were this would be very confusing and some of the other images (e.g. patient floating on a bed) would be without context. Assuming the audience knows what bedsores are and how they are treated could be a possible solution but you felt it necessary to explain that later.

4. **Were there any parts you found confusing or unclear?**

-Of course your video was an overview of the process rather than a specific set of directions, so I think the details left unclear, like exactly how to go about achieving the steps in this video, were outside your scope. So, within the scope and what seemed to be your goals, I think nothing was confusing/unclear.

-No

-Nope. The entire animation was crystal clear.

-Didn't initially understand why the main guy had pillows on his limbs. I think it's really cute, but maybe I would be able to follow it better if the pillows were going on a patient who then showed he couldn't grab things and then that whole scene "poofs" as a daydream.

5. **Did you find the characters and cartoon style appropriate? Why or why not?**

-Yes – it was clear and helped me as the viewer follow the process. The recurring characters and symbols, as well as the tracking chart in the bottom left, were especially helpful to this end. There was some understated humor in the animation which made the video more fun to watch without taking away from the technical subject matter or turning the video into outright comedy, which would have hurt the goal.

-It was fun. Love to see this with a bigger production budget.

-Yes, I loved it! This cartoon-like style livens up what could have been a boring animation. The subject material is dry, but the animation kept me engaged.

-Yeah! Very Expressive! Good gender balance! Could use more races!

-Absolutely! I found the characters informative (didn't take away from the message and weren't distracting) and kind of endearing but maybe that's just my strong association with that style and Calvin and Hobbes?

6. **Did you find yourself losing interest at any point? If so, where?**

-Not at all. I was rooting for the main character's design to succeed! I think I felt some genuine happiness and relief when the hospital administrator started seeing the benefit of the product.

-No. There were plenty of scenes changes to keep me focused.

-I found myself losing interest during the initial explanation of the various sectors, but I think this is unavoidable. The sectors have to be introduced so that you can go on to explain and illustrate

the spiral model. I think you did a good job as keeping the animations interesting during this part, and it helped me stick with the video.

-Nope. I want to know more about bed sores!

-The beginning was a bit rough as I was stuck on "Why is he trying to fix the problem like that?"

7. **Were you confused at any point with a symbol, or graphic?**

-I couldn't tell if the student was designing an alarm system or what, but I also don't think that's the point. I understood that the emergency light thing was a symbol representing whatever device they were actually working on. I know the point of the video was not actually to propose a solution to pressure sores, so I think that was just fine.

-No. I was confused about the butt being a pressure sore and the early graphic to identify what a pressure sore was. Figured it out.

-Nope! All of the symbols and graphics made sense to me.

-The sectors graphic in the bottom left could reflect the connectedness of the spiraling step-wise process instead of the current discrete segmentation. The time progression of the growing wedges is a nice touch, but (unless I'm misunderstanding) I think it could communicate information feeding into the next sector better.

-Nope! I thought the spiral with time as the axis was clear and pretty clever.

8. **Feel free to provide further feedback:**

-I loved this!! It was so easy to understand and beautifully combined being cute and engaging with being really informative. I hadn't heard of this particular process of innovation/development, and now I feel like I could explain it to someone else. Sarah loved it too (we watched it together). We're both so impressed. Go you! I can't wait to see the finished product.

-That was fun. Not sure why this is a new idea but it clearly conveyed as to how one would implement a new idea and get the idea into production.

-One suggestion I would have is to speed up the voice-over if possible. It was a bit too slow for my taste. The current speed is slow enough that I found my mind wandering at times. When I changed the playback speed to 1.25, I found myself much more focused on the animation and my mind wandered less.

-The main weaknesses I saw pertained to the background and context of the beginning. However, this did not detract from the overall communication of the necessity and basic mechanism of the Iterative Cycle.

References

1. Allen, R. H., S. Acharya, C. Jancuk, and A. A. Shoukas. “Sharing Best Practices in Teaching Biomedical Engineering Design.” Annals of Biomedical Engineering 41, no. 9 (2013): 1869-879. doi:10.1007/s10439-013-0781-y.

2. “Are we ready for this change?” AHRQ--Agency for Healthcare Research and Quality: Advancing Excellence in Health Care. October 02, 2014. Accessed March 19, 2018. https://www.ahrq.gov/professionals/systems/hospital/pressureulcertoolkit/putool1.html.

3. Krummel, Thomas M., Paul G. Yock, Stefanos A. Zenios, et al. Biodesign: the process of innovating medical technologies. Cambridge: Cambridge University Press, 2017.

4. Boehm, Barry W. “A Spiral Model of Software Development and Enhancement.” Readings in Human–Computer Interaction, 1995, 281-92. doi:10.1016/b978-0-08-051574-8.50031-5.

5. Farinella, Matteo. “The potential of comics in science communication.” Journal of Science Communication 17, no. 01 (2018). doi:10.22323/2.17010401.

6. “The Financial Impact of Pressure Ulcers.” Leafhealthcare.com. 2016. http://leafhealthcare.com/pdfs/LH_WP_FinancialOverview_1563AB_101316.pdf.

7. Manbachi, Amir, et al. “Starting a Medical Technology Venture as a Young Academic Innovator or Student Entrepreneur.” Annals of Biomedical Engineering 46, no. 1 (2017): 1-13. doi:10.1007/s10439-017-1938-x.

8. McCloud, Scott. Understanding comics. New York: Paradox Press, 2000.

9. “Purchase one license now.” TVPaint Developpement - Web Site. Accessed March 19, 2018. https://www.tvpaint.com/v2/content/article/store/other.php?country=US.

10. Szurmak, Joanna, and Mindy Thuna. “Tell Me a Story: The Use of Narrative as a Tool for Instruction.” Ala.org. April 10, 2013. http://www.ala.org/acrl/sites/ala.org.acrl/files/content/conferences/

confsandpreconfs/2013/papers/SzurmakThuna_TellMe.pdf.

11. “Toon Boom vs. Flash (Adobe Animate): Which One Should You Use?” Bloop Animation. February 26, 2018. Accessed March 19, 2018. https://www.bloopanimation.com/toon-boom-vs-flash-adobe-animate/.

12. Yazdi, Youseph. New Class Intro to Design Spirals. (2018) Pptx.

13. Yazdi, Youseph, and Soumyadipta Acharya. “A New Model for Graduate Education and Innovation in Medical Technology.” Annals of Biomedical Engineering 41, no. 9 (2013): 1822-833. doi:10.1007/s10439-013-0869-4.

14. Yazdi, Youseph. “Developing Innovative Clinicians and Biomedical Engineers.” American Journal of Preventive Medicine 44, no. 1 (2013). doi:10.1016/j.amepre.2012.09.013.

15. DisneyEducation. YouTube. December 08, 2011. Accessed March 19, 2018. https://www.youtube.com/watch?v=FFroMQlKiag.

16. D0MICS. YouTube. December 12, 2013. Accessed March 19, 2018. https://www.youtube.com/watch?v=tMWiYIVoDis.

Vita

Tziporah Thompson was born in Goleta, California, surrounded by goats, horses, and chickens. In 1999, she moved with her family to Los Angeles. She attended Shalhevet High School, where she was an active member of the school newspaper, drama club, orchestra, and choir.

Tziporah left high school a year early to study neuroscience at Brandeis University in Waltham, Massachusetts. During this time, she also worked as an illustrator for the school newspaper, as well as a lighting designer, technical coordinator, director, and scenic designer for several theater groups. Summers were spent volunteering in a neurophysiology lab at the University of California in Los Angeles, studying the effects of spinal cord stimulation on the locomotion of rats. She graduated cum laude from Brandeis with a Bachelor's of Science in 2014.

Immediately following graduation, Tziporah moved to Baltimore where she worked as the lab manager for the Human Brain Physiology and Stimulation Lab at the Johns Hopkins School of Medicine. In addition to organizing the research projects of numerous postdocs and Ph.D. students, she created illustrations for publication and rebuilt the lab's website. In the evenings, she took classes at the Schuler School of Fine Arts to study classic techniques in oil painting, watercolor, and charcoal drawings, while weekends were spent in figure drawing sessions at the Maryland Institute College of Art.

After two years of full time work, she was thrilled to be accepted into the Art as Applied to Medicine graduate program. During her studies, she was supported by the William P. Didusch Scholarship and earned a Research Grant Scholarship from the Vesalius Trust for her thesis work. Tziporah will graduate in May 2018 and looks forward to using her Master's degree to help foster life science literacy in exciting and visually engaging new ways.